Message

From: Caravelli, Margaret [mcaravelli@balch.com]
Sent: 6/5/2018 5:10:53 PM
To: Wildeman, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05dd0af69bfa40429e438b7646502b99-Wildeman, A]
CC: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Penman, Crystal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93662678a6fd4d4695c3df22cd95935a-Penman, Crystal]
Subject: RE: Water Related Rulemaking
Attachments: ATT00001.txt

Flag: Follow up

Anna:
I'll work with Crystal to get something scheduled. I may or may not be joined by client but will confirm with Crystal. Thank you and look forward to meeting you.

Regards,
Margaret

From: Wildeman, Anna [mailto:wildeman.anna@epa.gov]
Sent: Tuesday, June 05, 2018 7:24 AM
To: Caravelli, Margaret
Cc: Bolen, Brittany; Penman, Crystal
Subject: RE: Water Related Rulemaking

[External Email] Please use caution.

Hi Margaret,
I would be happy to discuss 316(b) with you. This week won't work for my calendar, but I've copied Crystal Penman on this email and she can help get something scheduled for next week.
Best,
Anna

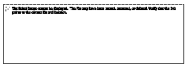
From: Caravelli, Margaret [mailto:mcaravelli@balch.com]
Sent: Monday, June 4, 2018 4:14 PM
To: Wildeman, Anna <wildeman.anna@epa.gov>
Cc: Bolen, Brittany <bolen.brittany@epa.gov>
Subject: Water Related Rulemaking

Hi Anna:
Reaching out to you in follow up to a brief conversation I had with Lee Forsgren last week. It's my understanding this is your first week or so at EPA HQ. By way of introduction I am a former House & Senate Committee Senior Counsel that handled the Clean Air Act.
I've included Brittany Bolen from the Office of Policy on this email because the inquiry also relates to regulatory reform of which I know Brittany is involved. Brittany and I are former colleagues from the Senate Environment and Public Works Committee.

Currently, I work with clients that have an interest in the 316(b) and certain aspects of its applicability. Is it best to schedule a meeting with you to discuss the 316(b) rulemaking and interpretative matters? Do you have a scheduler?

Please let me know if my request needs to be directly elsewhere. My contact information is below in the signature line. Thank you in advance.

Regards,
Margaret Caravelli



Margaret Caravelli, Partner, Balch & Bingham LLP
601 Pennsylvania Avenue, NW ◦ Suite 825 South ◦ Washington, DC 20004-2601
t. (202) 661-6342 Ex. 6 e: mcaravelli@balch.com
www.balch.com

Message

From: Heidi McAuliffe [hmcauliffe@paint.org]
Sent: 5/11/2018 7:33:45 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
CC: Kime, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ef7b76087a6475b80fc984ac2dd4497-RKime]
Subject: Request for meeting - Reg Reform

Flag: Follow up

Hi Brittany,

I hope that you are well and not too overwhelmed since Samantha's absence. Hopefully you will get a chance to relax this weekend.

I would like to meet with you to discuss some of ACA's regulatory reform priorities. Do you have some time available in the next couple of weeks?

I look forward to hearing from you.

Best, Heidi

Heidi K. McAuliffe ▪ American Coatings Association ▪ Vice President, Government Affairs
202- 719-3686 | Ex. 6 (m) | 202-263-1102 (fax) | hmcauliffe@paint.org | www.paint.org

901 New York Ave. NW, Suite 300 West ▪ Washington, DC 20001
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From: Kime, Robin [mailto:Kime.Robin@epa.gov]
Sent: Monday, November 13, 2017 10:07 AM
To: Heidi McAuliffe <hmcauliffe@paint.org>
Cc: Dravis, Samantha <dravis.samantha@epa.gov>
Subject: RE: Photo

Thanks again Heidi and yes, that is correct.
Take care

From: Heidi McAuliffe [mailto:hmcauliffe@paint.org]
Sent: Monday, November 13, 2017 9:46 AM
To: Dravis, Samantha <dravis.samantha@epa.gov>
Cc: Kime, Robin <Kime.Robin@epa.gov>
Subject: RE: Photo

Samantha,

My staff has removed the photo. If you refresh your browser on that page, you should be able to see that. Again, I apologize for any overstepping on my part.

From your last message, it sounds like you would like us to delete the paragraph which mentions your appearance. Is that correct?

Thanks, Heidi

Heidi K. McAuliffe ▪ American Coatings Association ▪ Vice President, Government Affairs
202- 719-3686 | Ex. 6 (m) | 202-263-1102 (fax) | hmcauliffe@paint.org | www.paint.org

901 New York Ave. NW, Suite 300 West ▪ Washington, DC 20001
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From: Dravis, Samantha [mailto:dravis.samantha@epa.gov]
Sent: Monday, November 13, 2017 9:30 AM
To: Heidi McAuliffe <hmcauliffe@paint.org>
Cc: Kime, Robin <Kime.Robin@epa.gov>
Subject: RE: Photo

If you could just take down the entire review post, I'd appreciate it.

From: Heidi McAuliffe [mailto:hmcauliffe@paint.org]
Sent: Monday, November 13, 2017 9:27 AM
To: Dravis, Samantha <dravis.samantha@epa.gov>
Cc: Kime, Robin <Kime.Robin@epa.gov>
Subject: RE: Photo

Samantha,

My apologies. I was not aware that a photo was going to be published. I had carefully reviewed the text to make sure that no comments or statements were attributed to you or any of our other speakers but I did not see any pictures at the time. I will have it removed immediately. It might take a few minutes as I don't know how to do it and will have to get to my IT staff quickly.

Again, I am sorry about that. Please accept my apology.

Best regards,

Heidi K. McAuliffe ▪ American Coatings Association ▪ Vice President, Government Affairs
202- 719-3686 | Ex. 6 (m) | 202-263-1102 (fax) | hmcauliffe@paint.org | www.paint.org

901 New York Ave. NW, Suite 300 West ▪ Washington, DC 20001
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From: Dravis, Samantha [mailto:dravis.samantha@epa.gov]
Sent: Monday, November 13, 2017 8:47 AM
To: Heidi McAuliffe <hmcauliffe@paint.org>
Cc: Kime, Robin <Kime.Robin@epa.gov>
Subject: Photo
Importance: High

http://www.paint.org/coatings-industry-policy-summit-review/

Heidi, I did not give you or anyone else permission to take photographs of me at my speaking engagement, and I certainly did not authorize one to be posted on the internet. This needs to come down, immediately.

Regards,
Samantha

Message

From: Robert Helminiak [helminiakr@socma.com]
Sent: 6/12/2017 10:11:02 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: SOCMA - Environment Committee Meeting

Hi Brittany,

I hope all is well. I'm following up on a message I left for you earlier today. We've met a couple of times since you joined EPA, most recently at a meeting with the Color Pigment Manufacturers Association last week.

SOCMA is holding its Environment Committee meeting on Wednesday. I reached out to Samantha Dravis and invited her to speak to the members, or for a recommendation of someone else. Candidly, I was hoping she would suggest you. Unfortunately, I haven't heard back from Samantha (it was short notice and I know how busy you guys are).

I was hoping you could take some time on Wednesday to talk to my members about the general direction of EPA. This group is broadly focused on environment issues (though TSCA is specifically OUTSIDE of their realm). The RMP news is something that is great for them. We would be happy to host you, or we could come to your office, or we could give you the call-in information.

Let me know if you have any questions. I look forward to your response.

Regards,
Robby

Robert F. Helminiak | *Managing Director, Government Relations*

Society of Chemical Manufacturers & Affiliates (SOCMA)
1400 Crystal Drive | Suite 630 | Arlington, VA 22202

D: 571.348.5107 | M: Ex. 6

Message

From: Rick MacPherson [rmacpherson@midwestemissions.com]
Sent: 9/15/2017 3:28:24 PM
To: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Dominguez, Alexander [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ced433b4ef54171864ed98a36cb7a5f-Dominguez,]
CC: Stacey Hyatt [shyatt@midwestemissions.com]; thomas Lorenzen [tlorenzen@crowell.com]
Subject: Follow up from Rick

Mandy,

I trust you have been busy since our meeting.

Please let me know if there is anything I can initiate from our end to get a proposed visit underway to a coal fired utility, in either Oklahoma or another state, by Administrator Pruitt.

I very much look forward to the opportunity to showcase how well our world class, EPA supported technologies, are working to keep the environment clean here in the USA.

Cheers,

Rick Macpherson
CEO
Midwest Energy Emissions Corp

Message

From: Laura Kasch [lkasch@afsinc.org]
Sent: 9/15/2017 7:06:22 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Lovell, Will (William) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b150bb6ade640f68d744fadcb83a73e-Lovell, Wil]
CC: 'doman@haleyaldrich.com' [doman@haleyaldrich.com]
Subject: 29th AFS EHS Conference Speaker Confirmation
Attachments: 29EHSConf_PptTemplate.pptx; 29thEHS CONF-AGENDA.docx

Importance: High
Flag: Flag for follow up

Dear Brittany,
Thank you for accepting our invitation to speak at the ***29th Environmental, Health & Safety Conference*** to be held October 31-November 2, 2017 at Hyatt Regency Birmingham – The Wynfrey Hotel. Attached is the latest version of the agenda. You will be afforded full complimentary registration to the conference.

To facilitate the publication of the conference proceedings and speaker information, please send us the following **on or before September 29, 2017**:

1) **Email me a copy of your PowerPoint presentation**. You can used the attached AFS template OR the official template of your agency.
   - If your presentation is over 10 megabytes, please upload to our FTP site: http://www.afsinc.net/uploadsite/index.asp. Username: consultant; Password: safe

2) **Submit your speaker bio form here:**
   - https://americanfoundrysociety.wufoo.com/forms/2017-ehs-conference-speaker-form/

Here are a few details to help your planning:

Hyatt Regency Birmingham
The Wynfrey Hotel
1000 Riverchase Galleria
Birmingham, AL 35244

AFS Room Rate $149 Standard / Double Guestroom
$169 Standard / Double – Regency Club*

AFS Room Rate includes complimentary internet in guest rooms and meeting space.

**Regency Club accommodations are located on restricted access floors and include private Concierge, continental breakfast and evening hors d'oeuvres in a private lounge.*

Reservations must be made no later than, **Friday, October 6**. Click this link to reserve a room at the conference rate: https://aws.passkey.com/go/AmericanFoundrySocietyOct2017.

Check-in time begins at 3:00 p.m. / Check-out time is 12:00 p.m.

The Hotel will extend the conference rate up to 2 days prior and/or 2 days following the conference arrival and departure dates, based on room and rate availability.

Airport Transportation
The Hyatt Regency Birmingham – The Wynfrey Hotel provides **complimentary** airport transportation for individuals. Reservations are **REQUIRED**.

Parking
Registered overnight guests will be provided parking in the hotel garage at the daily discounted rate of $10 and valet parking is available at $12 per day.

Again, thank you for agreeing to speak and for your prompt attention to this request. Your presence and materials are vital to the success of the conference. If you have any questions, please don't hesitate to contact me.

Sincerely,

Laura J. Kasch
Technical Assistant
American Foundry Society
1695 N. Penny Lane
Schaumburg, IL 60173
Phone: 847/824-0181, Ext. 246
lkasch@afsinc.org


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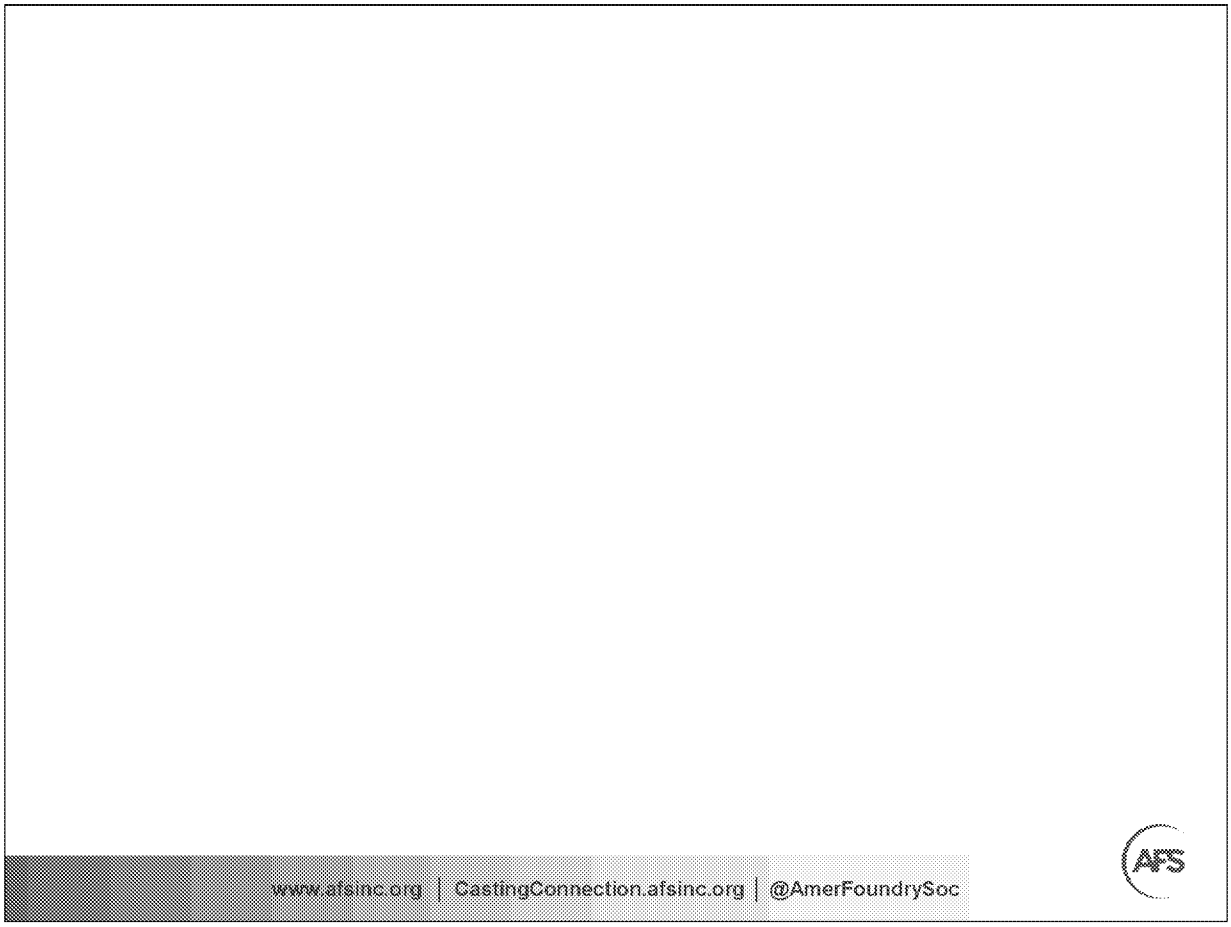
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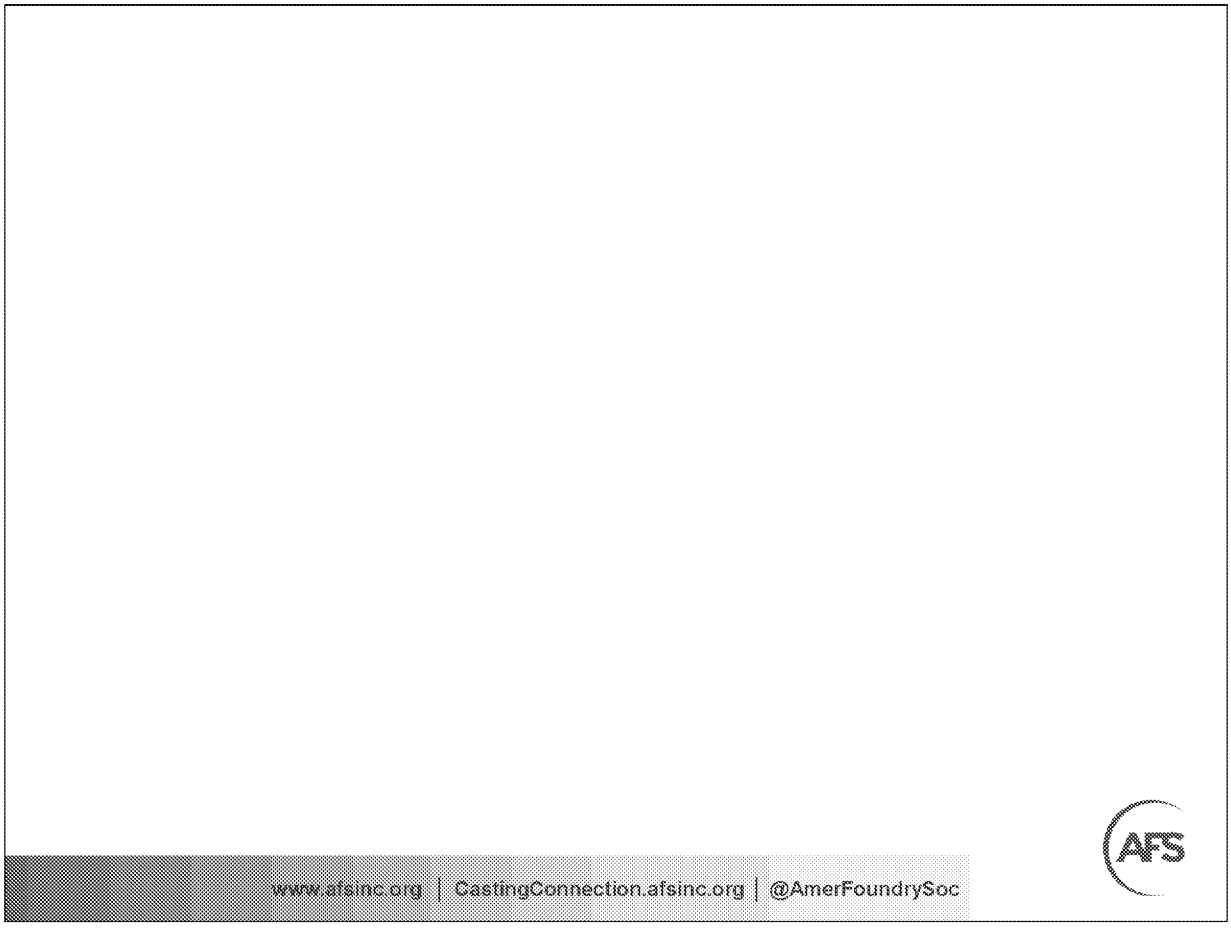
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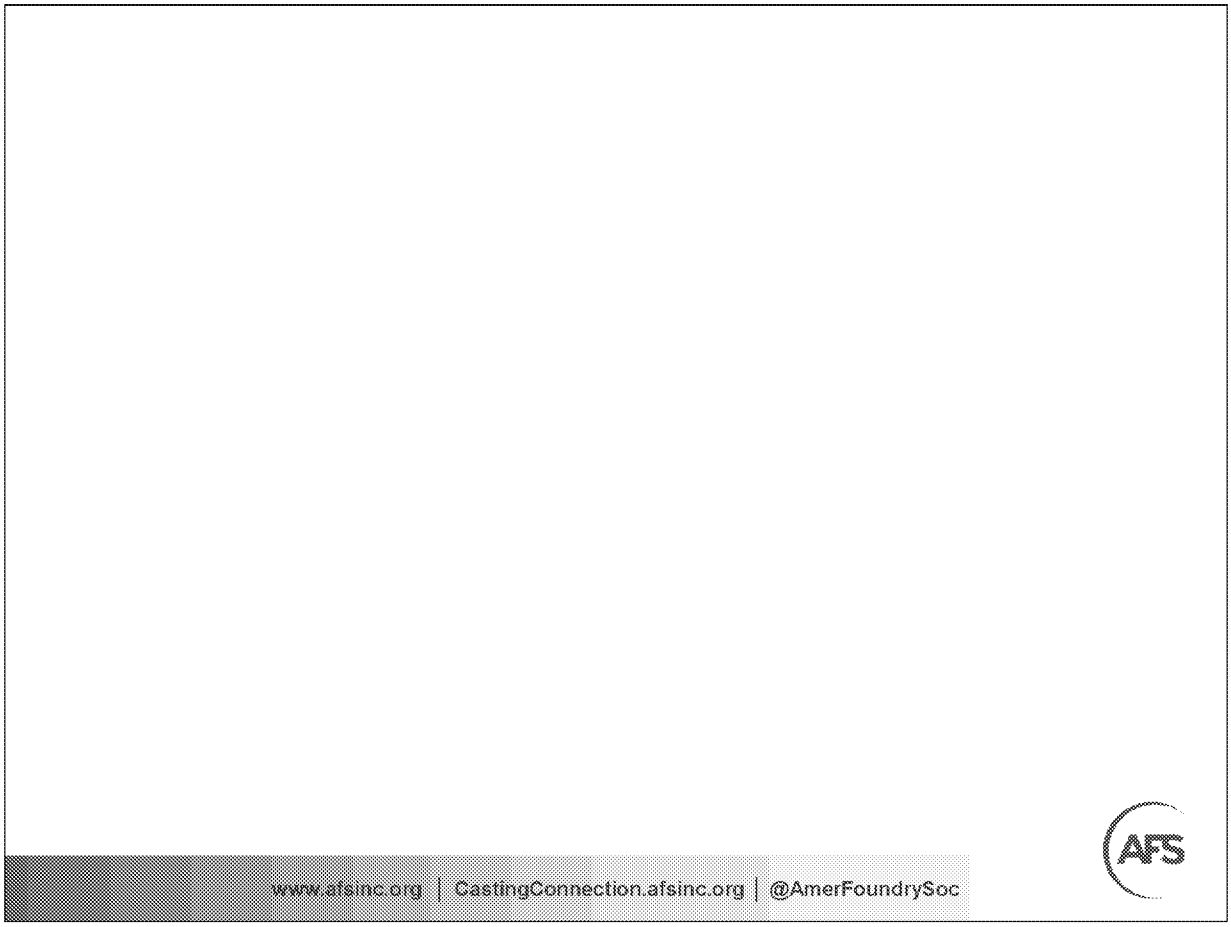
AFS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29th AFS ENVIRONMENTAL, HEALTH & SAFETY CONFERENCE
October 31 – November 2, 2017
Birmingham, AL
(Program, Speakers & Agenda Subject to Change)

TUESDAY, October 31, 2017 **Environmental Session**

7:00am-3:45 pm **CONFERENCE REGISTRATION**

7:00 am-8:00 am **CONTINENTAL BREAKFAST**

8:00 am-8:30 am **WELCOME / ANNOUNCEMENTS**
Dan Oman, Haley & Aldrich, Inc. AFS EHS Division (10) Chair

INTRODUCTION
- **Division 10 Committee Overview**
- **Recognition of Division 10 Members in Attendance**
- **CONFERENCE CO-CHAIRS**

8:30am-9:15 am **USEPA's Next Generation Compliance Initiative**
David Hindin USEPA Office of Enforcement and Compliance Assurance (invited)
- How EPA Is using Next Generation techniques to enhance enforcement and compliance
- Summary of advanced air monitoring technology

9:15am-10:00 am **Management of Change; Planning for compliance instead of reacting to change**
Greg Kramer, Corporate Environmental Engineer – ME Global, Inc.
Rob Campbell-Watt, Vice President of EHS Services - Arcadis
- Change happens
- Identifying the "gatekeepers of change" at each level of the organization
- Implementing controls that ensure the right people are involved when planning for change

10:00am-10:15 am **REFRESHMENT BREAK**

10:15am-11:00 am **Environmental Information Management Systems**
Ward Pate, McWane, Inc. and Jeff Cross, Dakota Software
- How EIMS Systems help achieve and maintain compliance
- The Benefits of an EIMS

11:00 am-11:45 am **Community Relations Foundry Panel**
Moderator: Mike Lenahan, Fairmount Santrol
Panelists: Bryant Esch, Waupaca Foundry
Dan Plant, Metal Technologies
Dave Robinson, AB&I
- Initiatives undertaken to proactively work with the community
- How to handle unplanned interruptions and challenges presented by the local community

11:45 am-12:45 pm **LUNCH**

12:45 pm-1:30 pm **Benchmarking Stormwater Compliance**
Larry Bowers; Group Environmental Compliance Director – McWane, Inc.
- Benchmarks: The good, the bad and the ugly
- What are "Best Industry Standards"
- Surviving a surprise EPA stormwater Inspection

1:30 pm-2:15 pm **Centralized Environmental Baghouse Monitoring Systems: Benefits, Limitations and Pitfalls**
Dave Sarvela, ME Global, Inc.

- Minimum requirements and maximum capabilities
- Advantages/Disadvantages of different types of systems
- Need for real-time and historical data from baghouses, associated equipment, and other environmental control equipment
- How data can be used to improve operational performance, identify trends and troubleshoot performance issues

2:15 pm-2:30 pm **REFRESHMENT BREAK**

2:30 pm-3:15 pm **Beneficial Reuse Foundry Panel**
Moderator: Mike Lenahan, Fairmount Santrol
Panelists: Earl Miller, Hiler Industries
Bill Crabtree, RRC
Bryant Esch, Waupaca Foundry
- Elements of a successful beneficial reuse project
- What does it take to get started?

3:15 pm-4:00 pm **Foundry Emission Factors Update**
Craig Schmeisser, Fairmount Santrol
- Presentation of AFS database of foundry emission factors
- Where do we go from here?

4:00 pm – 4:30 pm **Green Foundry Practices Update**
Holly Hurst, McWane Ductile-Utah
- What green practices have other metalcasters implemented?
- How can you showcase your best practices?

4:30 pm – 6:00 pm **Environmental Session for "Metalcasters Only"**
Moderator: Bryant Esch, Waupaca Foundry
Panelists: Tonya Burgess, Sivyer Steel Corporation
Jeet Radia, McWane, Inc.
Kim Myers, Amsted Rail/Griffin Wheel
Dan Plant, Metal Technologies, Inc.

WEDNESDAY, November 1, 2017 **Combined Environmental /Health & Safety Session**

7:00 am - 8:00 am **REGISTRATION / CONTINENTAL BREAKFAST**

8:00 am – 8:45 am **Regulatory Reform at USEPA**
Brittany Bolen, Deputy Associate Administrator at the Office of Policy, EPA

8:45 am – 9:30 am **Weathering an EHS Hurricane: A Case Study on the Value of EHS Compliance**
Jim M. Proctor II, Senior Vice President and General Counsel, McWane, Inc.
- Benefits of a robust EHS compliance program
- Consequences of ignoring or shortchanging EHS

9:30 am-10:15 am **Washington Update**
Stephanie Salmon, AFS Washington, DC
Jeff Hannapel, The Policy Group
- The immediate Impact of the New Administration on EPA and OSHA
- What can metalcasters expect from the New Administration going forward

10:15am-10:30 am **REFRESHMENT BREAK**

10:30 am-11:30 am **EHS Hot Topics**
Air Quality - Jeet Radia, McWane, Inc.
Water & Waste - Mark Remlinger, Matthews International
Health & Safety - Tom Slavin, Cardno ChemRisk

- What are the latest regulatory issues keeping metalcasters awake at night?
- How is AFS helping metalcasters anticipate and prepare for new regulatory impacts?

11:30 am-12:15 pm **The Role of Environmental Advocacy Groups**
Moderator: **Jeet Radia, McWane, Inc.**
Panelists: **Keith Johnston, Managing Attorney, The Southern Environmental Law Center**
Beth Stewart, Cahaba River Society
Cindy Lowry, Executive Director, Alabama Rivers Alliance

- Different approaches used with pro's and con's
- Explore ways in which we can work together

12:15 pm – 12:30 pm **DIVISION 10 AWARD PRESENTATIONS:**
AFS DIVISION INDIVIDUAL AWARDS
2017 AFS METALCASTING SAFE YEAR AWARDS

12:30 pm-1:30 pm **LUNCH with Exhibitors**

1:30 pm-2:15pm **Silica Litigation and OSHA Update**
Brad Hammock, Jackson Lewis

- Status of silica litigation
- Other silica legislative and regulatory developments

2:15 pm-3:00 pm **Silica Key Compliance Issues Panel**
Bob Scholz, TRC Environmental
Fred Simpson, McWane, Inc.
Tom Slavin, Cardno ChemRisk

- Focus on key compliance issues
- Question and answer format

3:00 pm-3:30 pm **REFRESHMENT BREAK with Exhibitors**

3:30 pm -4:15 pm **Dust Mapping**
Fred Simpson, McWane, Inc.

- How mapping has been used as a practical tool
- Benefits and lessons from first-hand experience

4:15 pm-5:00 pm **Improving the Performance of a Dust Collector**
Mike Johnson, Clarcor Industrial Air

- Common problems encountered in metal casting facilities
- Optimizing performance through predictive and preventive maintenance

5:30 pm- **ANNUAL RECEPTION with EXHIBITORS**
-Networking, an Exhibitor Experience, Hors D 'Oeuvres, & Refreshments for All

THURSDAY, November 2, 2017 **Health and Safety Session**

7:30 am-8:00 am	**REGISTRATION / CONTINENTAL BREAKFAST**
8:00 am-8:45 am	**PPE Changes You Should Know About** **Matt Block, Magid Glove** • Major changes in PPE technology and standards • Implications for foundry applications
8:45 am-9:15 am	**PPE Testing Presentation by UAB** **Robin Foley, University of Alabama Birmingham** • Molten metal splash protection equipment • How testing is done at UAB
9:15 am-10:00 am	**Highlights of the New ANSI/ASSE Z244.1 Lockout Standard – Benefits for Your Business** **Todd Grover, Master Lock** • What you should know about the ANSI standard • What it means for your lockout tagout program
10:00 am-10:15 am	**REFRESHMENT BREAK**
10:15 am-11:00 am	**Neptune Foundry Ventilation/Ergonomics Case Study** **Bob Forrester, Neptune Technologies and Ben Lemley, TRC Environmental** • Design of controls for casting cleaning task • Results and lessons learned
11:00 am-11:45 am	**Foundry Practices and Experiences in Controlling Silica Exposures** **Bob Scholz, TRC Environmental** • Common ventilation mistakes • Keys to making sure you get the performance and efficiency you pay for
11:45 am to 12:45 pm	**LUNCH**
12:45 pm-1:30 pm	**Top Ten Ways to Screw Up Your Ventilation System** **Marshal Rudman, Consultant** • Common ventilation mistakes
1:30 pm–2:15 pm	**Identification of Root Causes of Silica Exposure in Foundries** **Rebecca Ferrell, TRC Environmental** • Need for real time dust monitoring • Results of research on new equipment and methods
2:15 pm-3:30 pm	**Health and Safety Session for "Metalcasters Only"** **Moderator: Tonya Burgess, Sivyer Steel** **Panelists: Glenn Huneycutt, Charlotte Pipe** **Bob Forrester, Neptune Technology** **Fred Simpson, McWane, Inc.**
3:30 pm	**Adjourn**

Message

From: Oman, Daniel [DOman@haleyaldrich.com]
Sent: 9/15/2017 5:35:07 PM
To: Rees, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rees, Sarah]
CC: jhannapel@thepolicygroup.com [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e73026873e4e39ac26777c9b39f776-jhannapel@thepolicygroup.com]; Muller, Brad [BMuller@charlottepipe.com]; Stephanie Salmon [ssalmondc@gmail.com]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Lovell, Will (William) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b150bb6ade640f68d744fadcb83a73e-Lovell, Wil]; Kime, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ef7b76087a6475b80fc984ac2dd4497-RKime]; Laura Kasch (lkasch@afsinc.org) [lkasch@afsinc.org]
Subject: RE: American Foundry Society EHS Conference

Sarah,

This is great news. Thank you for following up on this and Brittany, thanks for "volunteering" to speak and the 2017 AFS EHS Conference in Birmingham, AL. I am going to cc Laura Kasch of AFS on this email and Laura will get in contact with Brittany (via Will) to make certain that you have the necessary information for making a presentation at our conference.

We are looking forward to Brittany's presentation at the conference.

Hope everyone has a great weekend and thanks again!
Dan

Dan Oman, P.E.
Senior Associate
Haley & Aldrich, Inc.
455 E. Eisenhower Parkway, Suite 210
Ann Arbor, MI 48108-3323

T: (734) 887.8404
C: Ex. 6

www.haleyaldrich.com

From: Rees, Sarah [mailto:rees.sarah@epa.gov]
Sent: Friday, September 15, 2017 1:26 PM
To: Oman, Daniel
Cc: jhannapel@thepolicygroup.com; Muller, Brad ; Stephanie Salmon ; Bolen, Brittany ; Lovell, Will (William) ; Kime, Robin
Subject: RE: American Foundry Society EHS Conference

Hi Dan - thanks so much for reaching out. We really appreciate opportunities to hear directly from regulated entities, and you guys have provided us with very helpful and constructive comments.

Brittany Bolen will be happy to speak at your conference. Brittany is the Deputy Associate Administrator at the Office of

Policy, and also a member of EPA's Regulatory Reform Task Force. I've cc'd Brittany on this email; please coordinate with Will Lovell (also cc'd) regarding logistics, etc. And if there is anything else you need from me, please let me know how I can be of service!

Cheers,
Sarah

-----Original Message-----
From: Oman, Daniel [mailto:DOman@haleyaldrich.com]
Sent: Thursday, September 14, 2017 3:22 PM
To: Rees, Sarah <rees.sarah@epa.gov>
Cc: jhannapel@thepolicygroup.com; Muller, Brad <BMuller@charlottepipe.com>; Stephanie Salmon <ssalmondc@gmail.com>
Subject: FW: American Foundry Society EHS Conference

Good afternoon Sarah,

I wanted to forward this email to you from Jeff Hannapel who is one of the American Foundry Society (AFS) representatives in Washington, DC. The AFS puts on an EHS Conference every year and this year the conference will be held in Birmingham, AL from October 31st thru November 2nd. On Wednesday November 1st we are hoping to have someone from USEPA give our membership a presentation on the Regulatory Reform process within the agency. As you note from Jeff's email, we as a trade association have provided comments to USEPA on two occasions regarding regulatory reform and we have also provided comments to the Department of Commerce.

Since we mentioned (and attached) the comments that we made to USEPA at your request, I thought I should make you aware of our request to the agency for someone to speak at our conference. Our membership is very interested in learning more about how regulatory reform is being implemented and a presentation by someone from the Office of Policy would be well received by the audience. I hope you will assist us in making this happen.

Finally, I wanted to remind you that AFS is committed to providing additional feedback regarding the air issues that were the subject of our July 29th letter to you. We have a number of industry experts within our EHS Division that are willing to meet with subject matter experts from USEPA to provide more detail and examples surrounding the comments that were in our letter. I made a similar offer to Patrick Davis via voice mail in August.

Please let us know how we can follow up on our meeting of June 20th and our letter of July 29th.

Thanks,
Dan Oman

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-----Original Message-----
From: Jeff Hannapel [mailto:jhannapel@thepolicygroup.com]
Sent: Wednesday, September 06, 2017 5:31 PM

To: Dravis.samantha@epa.gov
Cc: Bolen.brittany@epa.gov; Kime.robin@epa.gov; Oman, Daniel <DOman@haleyaldrich.com>
Subject: American Foundry Society EHS Conference

Ms. Samantha Dravis
Senior Advisor and Associate Administrator Office of Policy U.S. Environmental Protection Agency William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W. (1804A)
Washington, D.C. 20460

Re: Request to Speak at American Foundry Society EHS Conference

Dear Ms. Dravis:

On behalf of the American Foundry Society (AFS), I would like to invite you to present a review and update on EPA's regulatory review process at the AFS Environmental, Health and Safety (EHS) Conference in Birmingham, Alabama on November 1, 2017. AFS has been active in providing input to EPA on the regulatory reform process. For your reference, I have attached a copy of the regulatory reform comments that AFS submitted to EPA in May. In addition, representatives of AFS met with Administrator Pruitt's office in June and provided a follow up letter on regulatory reform issues in July, which is also attached. The current regulatory reform efforts appear to provide opportunities to minimize regulatory burdens on U.S. manufacturing, while continuing to promote superior environmental protection. We would be honored if you could make a presentation that focused on the regulatory reform process and how the agency is managing the process.

The annual AFS EHS Conference is attended by EHS professionals in the metalcasting industry and highlights the most critical EHS issues facing the metalcasting industry. We expect to have over 100 participants at this year's conference that is scheduled from October 31 to November 2. I would be happy to provide you with additional details on the AFS EHS Conference.

I hope that you or someone from your office would consider joining us at the AFS EHS Conference in Birmingham. If I can provide any additional information or answer any questions, please contact me by email or phone at 202-257-3756. I look forward to hearing from you soon.

Best regards,

Jeffrey S. Hannapel
The Policy Group
On Behalf of the American Foundry Society

Message

From: Lacey, Pam [PLacey@aga.org]
Sent: 7/13/2017 9:20:44 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: FW: Follow up meeting re: AGA and NGVA Regulatory Reform Comments (EPA-HQ-OA-2017-0190)
Attachments: AGA 05 15 2017 Comments on EPA Rule Review Docket EPA-HQ-OA-2017-0190.pdf; NGVA EPA Regulatory Review May 2017 Final.pdf

Dear Ms. Bolen:

It appears my email of June 28th may not have been delivered to you. Please see my note below and let me know whether you are available to meet next week, or if not, please suggest some dates in August that could work. AGA and NGVA would like to discuss EPA regulatory reform ideas with you and Ms. Dravis.

Best regards,

Pamela A. Lacey | Chief Regulatory Counsel
American Gas Association
400 N. Capitol St., NW | Washington, DC | 20001
P: 202-824-7340 | M: Ex. 6 | F: 202-824-9190 | placey@aga.org

From: Lacey, Pam
Sent: Wednesday, June 28, 2017 2:03 PM
To: Samantha Dravis (Dravis.samantha@Epa.gov) ; 'bolen.brittany@epa.org'
Cc: Clarke, Jeff ; Cunningham, Allison
Subject: Follow up meeting re: AGA and NGVA Regulatory Reform Comments (EPA-HQ-OA-2017-0190)

Dear Ms. Dravis and Ms. Bolen:

The American Gas Association (AGA) and Natural Gas Vehicles of America (NGVA) would like to arrange a follow-up meeting with you to discuss our ideas for regulatory reform, as described in our attached comments, filed May 15, 2017 in Docket EPA-HQ-OA-2017. NGVA General Counsel Jeffrey Clarke and NGVA Federal Government Affairs Director Allison Cunningham and I would like to meet with you and your team in July.

We are available anytime on Thursday July 14, the afternoon of Friday July 15, and anytime in the week of July 17-21 (other than 10:30 am – 1 pm on July 19 and 20. Please let me know what date and time you would prefer.

Respectfully,

Pamela A. Lacey | Chief Regulatory Counsel
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American Gas Association

Electronic Filing: www.regulations.gov

May 15, 2017

Ms. Samantha Dravis
Senior Counsel and Associate Administrator for Policy
Regulatory Reform Officer for Executive Order 13777
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Identification of Regulations for Repeal, Modification or Replacement under Executive Order 13777, 82 Fed. Reg. 17793 (April 13, 2017) (EPA Request for Comment) - **Docket No. EPA-HQ-OA-2017-0190**

Dear Ms. Davis:

The American Gas Association (AGA) appreciates the opportunity to suggest how certain EPA regulations could be repealed, modified or replaced to better serve EPA's mission, while reducing unnecessary duplication and burdens that divert resources from infrastructure projects and ongoing maintenance and upgrades needed to ensure the safe reliable delivery of energy. A more efficient approach will help achieve EPA's environmental goals in a less burdensome manner, and it will allow our members to channel more resources to improve their systems and increase good-paying, career utility jobs that sustain middle class families in communities across the country.

The American Gas Association, founded in 1918, represents more than 200 local energy companies that deliver clean natural gas throughout the United States. There are more than 73 million residential, commercial and industrial natural gas customers in the U.S., of which 95 percent — more than 69 million customers — receive their gas from AGA members. AGA is an advocate for natural gas utility companies and their customers and provides a broad range of programs and services for member natural gas pipelines, marketers, gatherers, international

natural gas companies and industry associates. Today, natural gas meets more than one-fourth of the United States' energy needs.

I. Air Office – Revise 40 C.F.R. Part 98 Subpart W and Repeal Subpart NN

A. Revise Subpart W to Reduce Unnecessary Burdens and Improve Accuracy:

The Subpart W Reporting Program is providing value to AGA members as a source of credible data to demonstrate their progress in reducing emissions. However, several revisions are needed to improve the accuracy of the data and to eliminate unnecessary cost burdens that divert resources from more productive, job-creating energy projects. We believe a few simple changes can achieve this goal.

1. Replace Unnecessary Leak Surveys with Emission Factors Based on Robust Data:

Companies in the natural gas industry have conducted annual Subpart W leak surveys of equipment since 2011, and now have a robust set of data that could be used to establish updated emission factors. While natural gas operators will of course continue to perform leak detection and repair to ensure safety - as required pursuant to Department of Transportation (DOT) pipeline safety regulations and related state requirements - there is no value or benefit in performing duplicative surveys using different timing and criteria for Subpart W. The surveys were originally required because EPA lacked data on certain emission sources. The costly Subpart W surveys can now be replaced with a simple arithmetic calculation using emission factors based on data collected to date. An emission factor approach for calculating GHG emissions is common for many sources in Subpart W, as well as other industries that report under the Part 98 reporting program.

This change should be made to eliminate, for example, Subpart W leak surveys under 40 C.F.R. 98.233(q) for natural gas Transmission to Distribution pressure reduction stations (T-D transfer stations), Liquefied Natural Gas (LNG) import-export terminals, peak-shaving LNG storage facilities, and transmission compression facilities. Instead of continuing these costly annual surveys, EPA should establish default emission factors based on the past six years of

reporting data, with an option for companies to use their own company-specific emission factors based on their own past Subpart W leak survey data.

Similarly, transmission compressor station and underground storage operators are required to conduct annual leak measurements under 40 C.F.R. 98.233(o) and (p) for reciprocating and centrifugal compressors, and under 40 C.F.R. 98.233(k) for scrubber dump valve leakage through condensate storage tank vents. These costly annual surveys should be replaced with default emission factors based on the past six years of reporting data, with an option for companies to use their own company-specific emission factors based on their own past Subpart W leak survey data. The leak survey requirement for other compressor station or storage facility components required under 40 C.F.R. 98.233(q) should also be replaced with emission factors.

2. Improve Accuracy by Updating Emission Factors to Reflect Current Practices:

To improve the accuracy of Subpart W data, EPA should update the default emission factors promptly as new, reliable scientific data becomes available. For example, Subpart W should use the same updated emission factors for natural gas distribution pipe as are already adopted for use for the annual EPA Inventory, based on the peer-reviewed study by Dr. Brian Lamb at Washington State University (WSU) published in the Journal of Environmental Science & Technology (March 2015). It is inaccurate and, frankly, misleading to continue overestimating natural gas emissions by using emission factors developed in a study conducted more than 20 years ago that evaluated a much smaller data set and reflected emissions from equipment and practices that have changed and improved dramatically since 1992. Additional robust data is expected to be available in 2018 from a series of studies co-funded by industry and Department of Energy (DOE). The Subpart W default emission factors should be updated as that new data becomes available.

As to the emission factor for metering and regulating (M&R) equipment in particular, there is also no legitimate reason to continue applying an outdated and highly-inflated emission factor to this equipment. At least in the past, EPA appears to have been under the impression that M&Rs emit more if they are located below grade rather than above grade. Modern

measurement data demonstrates this is not true. The same type of equipment is used in both above and below grade M&Rs and their emissions are far lower than the outdated default emission factor implies. EPA already allows up-to-date, company-specific emission factors for above grade M&Rs. The agency should allow the same updated emission factor for below grade M&Rs – based on the past six years of Subpart W emission surveys.

3. Eliminate Subpart W Throughput Reporting:

EPA should delete the recently added requirements in 40 C.F.R. Part 98, § 98.236(aa)(9) to report the quantity of natural gas received, delivered, stored, consumed and stolen. This provides no useful data for the purposes of Part 98 and duplicates natural gas throughput reporting under Subpart NN, which in turn already duplicates reporting to the DOE Energy Information Administration (EIA), as we note below.

B. Eliminate Throughput Reporting under Subpart NN:

EPA should review Subpart NN and consider, in a notice and comment rulemaking, whether to repeal it. At a minimum, Subpart NN reporting of natural gas deliveries to customers should be eliminated for natural gas distribution companies (LDCs), as this largely duplicates data companies are required to report to the DOE EIA and serves no useful purpose. The volume of natural gas delivered to customers in any year is mainly a function of annual weather fluctuations (i.e. colder or warmer winters), not commercial or industrial process changes.

II. Water Office

Review and Revise Waters of the U.S. Rule:

The Administration has already initiated a review of the federal rule defining the scope of waters of the United States (WOTUS). We want to emphasize the need for a revised rule that provides a clear dividing line between water features that are or are not subject to federal jurisdiction – without the need for subjective, arbitrary and unduly burdensome case-by-case

decisions that can delay natural gas utility and pipeline projects, impede job creation, impede economic development projects to be served by the pipeline, and increase costs.

III. OEM - Federal Standards for Aboveground Storage of Hazardous Substances

AGA is a member of the Utility Solid Waste Activities Group (USWAG), and we support USWAG's request that the Office of Emergency Management (OEM), within EPA's Office of Land and Emergency Response (OLEM), should avoid duplicative, unnecessary or proscriptive requirements in the pending federal standards for the aboveground storage of hazardous substances. This rulemaking is of interest to AGA because it could adversely affect operations for natural gas utilities. We agree with USWAG that any such regulatory program should allow for performance-based controls, as a more prescriptive approach could harm job creation, impose unnecessary burdens, and/or impose costs that exceed benefits.

IV. ORCR — Revise RCRA Generator Requirements for Remote Sites

AGA also agrees with USWAG that EPA should revise a recent final rule regarding hazardous waste generator requirements that imposed many stringent changes without commensurate improvements in environmental safety. The rule originated in OLEM's Office of Resource Conservation and Recovery (ORCR).[1] Of particular concern for natural gas utility operations is a provision in the preamble of the rule in which EPA "clarified" that states were not permitted to provide relief for the consolidation of hazardous wastes from remote or unstaffed sites. As USWAG notes, EPA provided limited relief for this type of consolidation in the final rule and then contended that state programs that had provided other types of commonsense relief for the same concerns were not permitted under the hazardous waste regulations.[2] This is highly disruptive for utility operations, particularly given that several states have already provided relief by allowing unknown wastes to be collected and consolidated from remote sites and postponing

[1] 81 Fed. Reg. 85732 (Nov. 28, 2016).
[2] *Id.* at 85776.

hazardous waste determinations until the waste is received at a staffed facility, or by authorizing the direct transfer of hazardous waste to central locations. A similar problem arises in the preamble where EPA suggests that the relief the rule offers is the only available for episodic generation events, when in fact, some states have used their enforcement discretion to address abnormal hazardous waste generation patterns. We urge EPA to acknowledge and encourage the availability of state programs, such as the ones mentioned above, that achieve equivalent environmental protections in a far more practical and cost-effective manner. This would be consistent with the role of RCRA-delegated states as the primary regulator for facilities located within their jurisdictions.

V. OPPT & ORCR - Revise and Simplify Federal PCB Regulation

EPA should review, revise and simplify certain provisions in the federal regulations governing the use, remediation and disposal of polychlorinated biphenyls (PCBs). The PCB regulations adopted in 1998[3] under 40 C.F.R. Part 761 were tailored to the agency's understanding of interstate pipelines, not natural gas local distribution systems, and are long overdue for modernization and simplification.

Under the Toxic Substances Control Act (TSCA) Section 6(e) (15 U.S.C. § 2605(e)), the use of PCBs other than in a "totally enclosed manner" was banned after 1977 except as authorized by EPA regulatory action. EPA included a use authorization with respect to PCBs in pipeline systems because an EPA-commissioned human health risk assessment in 1984 demonstrated the PCBs in enclosed pipelines do not pose an unacceptable risk to human health. PCBs were used in the last century as a fire retardant to improve safety in some products such as compressor lubricants and electric transformer fluid, but their manufacture and purchase ended in the last century. Their occasional presence and discovery makes it appropriate for EPA to maintain some form of "use authorization," but this can be

[3] The so-called "PCB Mega Rule" in 1998 was last significant amendment to the PCB regulations. See 63 Fed. Reg. 35384 (June 29, 1998).

accomplished in a less burdensome manner, especially for operators that did not originally introduce PCBs into their own systems, but rather received them from an upstream source.

The use authorization rule is now a relic of a former time, and the rule makes even less sense now than it did originally. EPA staff have recognized this and have suggested they may consider a new approach – replacing the old rule with a very simple authorization for the presence of PCBs in natural gas utility and pipeline systems, provided the operator follows reasonable requirements for managing and disposing of PCBs when they are discovered.

The use authorization rule for natural gas systems, administered by the Office of Pollution Prevention and Toxics ("OPPT") within EPA's Office of Chemical Safety and Pollution Prevention ("OCSPP") could be boiled down to a few words, eliminating significant and completely unnecessary cost burdens and complexity, as we explain below. The disposal and remediation rules in Part 761 are generally more risk-based and functional, but they too could be improved to eliminate some provisions that impose severe and unnecessary costs. Because the use authorization and disposal rules are interrelated but administered by two different offices at EPA, their revision should be coordinated. In fact, pursuant to Executive Order 13781 (March 13, 2017) establishing a comprehensive plan for reorganizing the Executive Branch, it would make sense to reduce confusion and duplication by consolidating the two functions and moving any remaining use authorization issues into one PCB use, remediation and disposal group within the Office of Resource Conservation and Recovery (ORCR) under the Office of Land and Emergency Management (OLEM).

A. Revise and Simplify PCB Use Authorization

Having a simple yet effective PCB use authorization is important to affected natural gas companies as they continue to rid their systems of PCBs over time. The existing use authorization rules governing PCBs in natural gas systems, however, are replete with vague, confusing, cumbersome, burdensome and irrational provisions, particularly for local natural gas distribution utilities. The confusion stems in part from trying to create natural gas regulations on a foundation of electrical equipment regulations developed 40 years ago, when in fact, the

use of PCBs in electric and gas systems was completely different. The confusion in the 1998 natural gas regulations also stems from the fact that EPA developed the regulations based on the agency's partial understanding of the interstate natural gas transmission pipelines where PCBs were discovered by EPA, and a complete misunderstanding about how local distribution systems operate. For example, the existing rule was drafted based on an incorrect assumption that both transmission and distribution systems are comprised of straight, level pipelines that flow in only one direction for many miles. Another misunderstanding that has caused serious confusion and excessive costs relates to the "source" of legacy PCBs in systems. A local distribution company that did not introduce PCBs into its own system, but rather received PCBs from an upstream interstate pipeline, does not have a source of PCBs in its system, yet it can become subject to the unduly burdensome use authorization requirements to eliminate "sources" that do not exist under such circumstances. These and other problems related to the use authorization rule have been compounded as local distribution systems have modernized and grown since 1998.

We encourage EPA to repeal the current use authorization regulations in 761.30 and replace them with a simple statement that liquid and non-liquid PCBs and PCBs in porous surfaces are authorized for use at any concentration in electric utility, natural gas distribution utility, storage and pipeline systems and operations, provided the operator complies with applicable requirements for PCB remediation, storage and disposal under Sections 761.60, 761.60, 761.61, 761.65, and 761.120 as PCBs are removed and eliminated from pipeline systems over time. We also urge EPA (1) to eliminate any reference to "potential sources,"[4] (2) clearly eliminate any flawed concept that devices designed to remove liquids (and PCBs if present) from natural gas systems somehow reintroduce them, and (3) eliminate extensive, unnecessary procedures for "characterizing" natural gas systems to look for PCB deposits today -- long after they were first introduced more than 50 years ago. Resources should instead be focused on responding appropriately and reasonably when any remaining PCBs are found.

[4] *See* 40 C.F.R. § 761.30(i)(1)(iii)(A).

Requirements for such response and disposal should be based on standard best practices that are self-implementing and clearly described in the rule, to eliminate the need for any EPA involvement in day-to-day operations.

B. Revise Certain PCB Analysis, Storage and Disposal Regulations

1. Change PCB Rules to Facilitate Gas & Electric Utility Operations

AGA agrees with USWAG that EPA should: (1) allow disposal of PCB remediation wastes at "as-found" levels <50 ppm in non-TSCA landfills; (2) modify the PCB analytical rules at 40 C.F.R. § 761.272 to expressly authorize the use of the automated soxhlet extraction procedure (Method 3541) for the chemical extraction of PCBs from individual and composite samples; and (3) amend 40 C.F.R. § 76165 to allow satellite accumulation of PCBs.

2. Change Storage and Disposal Rules to Facilitate Natural Gas Utility Operations

a. Reduce Costs by Allowing Rational Method to Identify Areas Not Subject to PCB Concerns and Disposal Restrictions

EPA's PCB disposal rules under Section 761.60 describe how to characterize and manage natural gas distribution and transmission pipelines from PCB-impacted systems when no longer fit for service, including restrictions on how pipe can be abandoned in place or disposed of, depending on PCB levels.[5] Pipe removal and replacement are becoming more common in response to DOT pipeline safety regulations, so the cost of complying with the PCB regulations for natural gas systems continues to rise while PCB levels continue to decline.

Natural gas companies strive to rid their systems of liquids in general and PCBs in particular to eliminate these added costs. However, it is not clear under the existing rules how an operator can "delist" a system or portion thereof from the costly and onerous pre-requisites for abandoning pipe in place. Nor are the rules clear regarding how and where to send pipe for disposal or recycling once PCBs are no longer found in the system or a portion thereof above the regulatory threshold. It is wasteful and very costly to continue applying restrictions designed for systems with PCBs in liquids to dry pipe that has salvage value and no longer poses a risk. Testing each section of pipe as it is taken out of service in such systems is also costly and

[5] See 40 C.F.R. § 761.60(b)(5).

wasteful. We would welcome the opportunity to work with EPA to develop a rational method for "delisting" systems or portions of systems that actually results in some incremental environmental benefit, so that resources can be focused on projects that improve safe and reliable energy delivery, create good paying utility jobs, and facilitate economic development.

b. Allow PCB Bulk Product Waste Storage or PCB Bulk Remediation Waste for Storage Up to 180 Days -- in a Roll-Off or Similar Container -- at Either the Site of Generation or Other Company-Owned Site

Pipe wrap and cathodic protection are two effective methods that have been used over the years for protecting metal pipe from corrosion. Coal tar pipe wrap was often used on steel and cast iron pipe for gas utility systems in the first half of last century. Sometimes oil containing PCBs was applied to the wrap to improve its flexibility. Gas utilities have been removing and replacing cast iron pipe over recent years as they modernize their systems, and they sometimes encounter sections of coal tar pipe wrap that contain PCBs at concentrations of $\geq$ 50 ppm. In such cases, utilities need a cost-effective method for managing this waste.

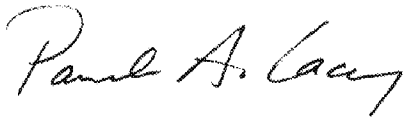
AGA agrees with USWAG that PCB-containing Coal Tar Wrap (CTW) material meets the definition of "PCB bulk product waste" under 40 C.F.R. § 761.3. The existing PCB storage regulations at 40 C.F.R. § 761.65(c)(9) allow temporary storage of PCB bulk product waste or PCB bulk remediation wastes at the site of generation for up to 180 days, but only in a "pile" that meets several restrictive performance standards. A better, simpler and more cost-effective option in many circumstances would be to use a roll-off or similar container. AGA agrees with USWAG that the rule should be amended to allow the use of a roll-off or similar container.

Further, since the site of generation could be in a city street or utility right-of-way, it is often not feasible or the best environmental option to store bulk PCB remediation wastes or bulk PCB product wastes there. It is often more practical and environmentally sound to bring such bulk wastes back to a utility service center or other company-owned central site. The existing regulations at 40 C.F.R. § 761.65(c)(1) allow operators to move PCB bulk product waste or PCB remediation waste from the site of generation back to a company-owned site for temporary storage before shipment off-site to a qualifying TSCA disposal facility – but such temporary storage at a company-owned central site (other than the site of generation) is limited to only 30

days. This short time period often does not allow adequate time for cost-effective storage prior to off-site shipment. For the reasons explained in USWAG's comments in this docket, extending this time period would not present an unreasonable risk of injury to health or the environment. EPA should amend its storage for disposal regulations at 40 C.F.R. § 761.65 to expressly authorize operators to move PCB remediation wastes and PCB bulk product wastes such as CTW or pipe covered with CTW from remote sites to a central company-owned location for storage up to 180 days.

AGA appreciates the opportunity to comment. If you have any questions, please contact me.

Respectfully Submitted,



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May 15, 2017

Ms. Samantha Davis
Senior Counsel and Associate Administrator for Policy
Regulatory Reform Officer for Executive Order 13777
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Identification of Regulations for Repeal, Modification or Replacement Under Executive Order 13777, 82 Fed. Reg. 17793 (April 13, 2017) (EPA Request for Comment) - Docket No. EPA-HQ-OA-2017-0190

Dear Ms. Davis:

NGVAmerica appreciates the opportunity to provide comments on the U.S. Environmental Protection Agency's regulatory review effort announced on April 13, 2017.

NGVAmerica is a national trade association dedicated to creating a profitable, sustainable and growing market for compressed natural gas, liquefied natural gas, and renewable natural gas powered vehicles. NGVAmerica represents more than 200 companies, including vehicle manufacturers; natural gas vehicle component manufacturers; natural gas distribution, transmission, and production companies; natural gas development organizations; non-profit advocacy organizations; state and local government agencies; and fleet operators.

The United States is the world's largest producer of clean-burning natural gas. The abundance of this domestic resource means that it is a clean, low-cost, stable energy source that can secure America's energy needs for decades to come. Using more domestic natural gas results in expanded job opportunities for workers that produce this fuel and it also provides cost-savings for the consumers and businesses that consume this fuel. It also adds much needed revenue to the state budgets in areas of the country where natural gas is produced.

To expand the opportunities for using this domestic fuel here in the U.S., more should be done to ensure that the right types of incentives and common sense regulations govern its use in the transportation sector. Using compressed natural gas (CNG), liquefied natural gas (LNG), and renewable natural gas (RNG) in transportation can displace demand for imported energy and deliver the lowest emissions among all fuels.

NGVAmerica offers the following comments relating to the regulation of natural gas vehicles. The requested regulatory and policy changes are intended to remove unnecessary impediments to the increased use of natural gas vehicles and domestic natural gas resources and, if adopted, will promote job creation, clean air, reduced emissions of greenhouse gases, and improved energy security.

I. Amend the Driving Range Requirements for NGVs to provide fair treatment relative to other technologies, and to provide additional incentive for manufacturers to produce natural gas vehicles

EPA should remove the requirements in 40 CFR § 600.510–12, *Calculation of average fuel economy and average carbon-related exhaust emissions*, part (c)(2)(vii)(B) for fuel economy and (j)(2)(vii)(B) for emissions, that require NGVs to have a driving range on natural gas that is two times the driving range on gasoline or diesel fuel. This requirement is wholly impractical as it would require automakers to install significantly larger and more expensive natural gas fuel systems on dual-fuel vehicles, or alternatively require automobile manufacturers to reduce the size of gasoline fuel systems installed on dual-fuel NGVs, to access the utility factors available to other vehicles. This latter requirement would impose significant costs as it would require the design and manufacturer of smaller gasoline tanks and changes in the assembly production of base gasoline vehicles to fit vehicles with unique gasoline tanks.

NGVAmerica previously petitioned EPA to remove this requirement but to date EPA has not acted on this petition. We would again urge EPA to revisit this issue and amend its regulations accordingly by removing this burdensome and unnecessary requirement. Amending the rules as requested would level the playing field with other technologies and increase the incentive for manufacturers to offer more light duty NGVs. It also could be expected to encourage manufacturers to begin to commercial new low-pressure and absorbed natural gas systems.

NGVAmerica wishes to indicate its support for separate comments submitted by VNG.CO addressing this same issue, and would appreciate an opportunity to provide additional information in support of this request.

II. Amend the marine engine certification requirements for dual-fuel natural gas engines so that compliance is based on the intended use of these engines and recognizes that when operating on natural gas/diesel mixtures these engines comply with and exceed the Tier III requirements. 40 CFR Part 1042 – Control of Emissions from New and In-Use Marine Compression-Ignition Engines and Vessels.

Natural gas, including liquefied natural gas, holds significant potential to displace petroleum as marine fuel and reduce emissions of harmful pollutants. Today, there are over 200 LNG ships in operation and on order. About 15 percent of new orders for these ships will operate in the US waters. There is growing interest in using LNG because it is a virtually sulfur free fuel and offers a significant reduction in particulates and NOx emissions compared to conventional marine fuels. LNG also provides a reduction in greenhouse gas emissions. In addition to the environmental benefits, encouraging the use

of more LNG as a fuel for marine vessels will lead to new economic development as bunkering facilities, ships and other fueling infrastructure are built to support this market.

In the US, Tier III NOx requirements are in effect for all category 3 new built vessels (range in size from 2,500 to 70,000 kW (3,000 to 100,000 hp) – large engines that propel ocean-going vessels such as container ships, oil tankers, bulk carriers, and cruise ships). The more demanding NOx emission levels required by the Tier III regulation is readily met by ships when they operate on LNG. In fact, using LNG results in NOx emissions that are well below required levels. To use LNG, most marine vessels rely on dual-fuel operation, which here refers to operation on a mixture of LNG and diesel fuel in a diesel cycle or compression-ignition engine.

The problem today is that the Tier III emission regulations do not distinguish between fuel types, or provide any allowance for dual-fuel engines that operate on mixture of LNG and diesel fuel. The regulations therefore require that these vessels meet the NOx emission levels on both fuels including when operating on 100 percent diesel fuel even though that is not how the dual-fuel engines are intended to operate. The result is that manufacturers must equip their dual-fuel natural gas/diesel engines with expensive after-treatment equipment (Selective Catalyst Reduction – SCR – Technology) that is not necessary to achieve the required emission levels. Installing SCR systems on these vessels adds an additional cost of 1 - 2 million dollars per ship, even for ships utilizing diesel only for ignition purposes and whose fuel use is primarily LNG.

While the number of LNG powered vessels is growing, economies of scale are not yet reached, and the expertise and knowledge in building these ships is still fledgling, especially in the US/Jones Act vessels. The fact that ship builders must install costly SCR systems can and does discourage the development of the market for LNG ships and the use of natural gas in the marine market.

NGVAmerica requests that EPA amend it rules to allow a waiver for dual-fuel engines that operate the majority of the time on LNG and that have demonstrated through testing that they meet the Tier III NOx regulation when operating as intended (e.g., 70%NG/30% diesel or 90%NG/10% diesel). Providing this waiver will stimulate growth and jobs in shipbuilding in the US and encourage a faster paced adoption of cleaner-burning natural gas in this market.

III. Amend the DERA Program to remove scrappage requirement for replacement vehicles that exceed current federal standards by 50% or more for NOx emissions

This issue concerns EPA guidance for the Diesel Emission Reduction Act (DERA) Program. Current guidance provides additional funding (i.e. 35% instead of 25%) for the cost of new replacement vehicles that have been certified to optional low-NOx standards. Thus, the program provides a larger incentive for cleaner engines. NGVAmerica strongly supports this provision as it currently stands but also urges EPA to expand the incentive for low-NOx engines by providing a larger incentive, or by removing the scrappage requirement.

The DERA program seeks to ensure emission reductions by removing older, dirtier equipment from operation. The removal of more polluting equipment is ensured by requiring scrappage of vehicles and engines. Assuming equipment is retired earlier than it otherwise would be the case, this essentially locks in excess emission reductions. Scrappage however comes at a cost for businesses that lose the opportunity to sell their equipment and receive compensation for the remaining value. For new diesel vehicles, it can be argued that providing 25 percent incentive for the cost of new replacement vehicle is more than sufficient to offset the economic loss associated with scrappage, and still provide an incentive to encourage the purchase of new, cleaner vehicles.

For natural gas vehicles, however, the DERA incentive of 25 percent or even 35 percent for the cost of a new vehicle is not sufficient to cover the economic loss associated with scrappage and the added costs associated with new natural gas trucks, which, like other advanced technology vehicles, cost more than conventionally fueled diesel vehicles. To remedy this situation, we would urge EPA to consider providing an even larger incentive for natural gas low-NOx vehicles. This could include providing 50 percent of the purchase for low-NOx alternative fuel trucks, or removing the scrappage requirement for low-NOx trucks. Such a policy would align with the DERA intent by delivering additional emission reductions because low-NOx engines are 50 – 90 percent cleaner than required.

IV. Amend the testing and sampling requirements for cellulosic fuel produced in anaerobic digesters to be less burdensome and encourage increased production of qualifying cellulosic fuel

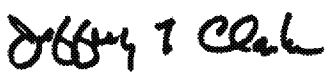
Renewable natural gas produced from a variety of feedstocks has proved to be a huge success story, and today accounts for a significant portion of natural gas used to fuel natural gas vehicles. This clean-burning, low-carbon fuel accounts for more than 20 percent of all on-road natural gas demand and is expected to account for more than 40 percent of on-road demand by 2018. The success of renewable natural gas is due in no small part to the inclusion of various incentives and regulatory programs that encourage the production of this fuel including the U.S. EPA's Renewable Fuel Standard (RFS) Program.

To expand the opportunity for renewable natural gas and remove burden on industry, NGVAmerica requests that EPA address the sampling and testing requirements required for anaerobic digesters (AD) that process crop waste to produce cellulosic fuel. AD producers have indicated that the testing requirements to demonstrate that 75 percent of the feedstock used in these facilities is cellulosic based are too burdensome and therefore discourage the production of more cellulosic qualifying fuel. Specifically, we request a change in the testing requirements found in 40 CFR 80.1426 so that instead of requiring the testing of every truck load that is delivered to an AD facility, that the testing is instead done quarterly and on random samples.

Conclusion

NGVAmerica appreciates the opportunity to provides these comments and would welcome the opportunity to discuss these issues further with EPA as it moves forward with its regulatory review. In addition to the comments offered here, NGVAmerica would like to offer its support for the comments submitted in the docket by VNG.CO, which address several other issues related to the certification of light duty vehicles that are not included in our submission but nevertheless we strongly support. We believe that the changes requested will provide more fair treatment for NGVs and level of the playing field with other transportation technologies, and thereby increase the use of domestic natural gas as a transportation fuel.

Sincerely,



Message

From: Heidi McAuliffe [hmcauliffe@paint.org]
Sent: 5/17/2017 5:00:21 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; David Darling [ddarling@paint.org]
CC: Andy Doyle [adoyle@paint.org]
Subject: ACA's Comment Letter on EPA Reg Reform
Attachments: Dravis Ltr. Reg Reform 5.15.17 final.pdf

Hi Brittany, I hope you are doing well and that you have a lot of help sifting through the 55,000 + submissions to the reg reform docket!!

I am sharing ACA's comments with you directly as we discussed. Our comments stick to the format that we talked about so that you can discern the issue, impact, costs and suggested solution quickly. We would be happy to follow up with you and provide additional information on any of the issues that we have highlighted. In a recent coalition meeting, Samantha Dravis suggested that trade associations point out some of the smaller regulatory distractions that impede innovation and are burdensome. I believe that we have provided several examples of significant issues like the Ozone rule but also some of the smaller ones like the triennial reporting in the aerosol coatings regulation.

Thank you for your willingness to take a look at our suggestions. I would like to follow up with you in the next few weeks to discuss any priority issues that catch your eye.

Please let me know if you have any questions at all,

Heidi

Heidi K. McAuliffe ▪ American Coatings Association ▪ Vice President, Government Affairs
202- 719-3686 | Ex. 6 (m) | 202-263-1102 (fax) | hmcauliffe@paint.org | www.paint.org

901 New York Ave. NW, Suite 300 West ▪ Washington, DC 20001
Coatings protect. Coatings preserve. Coatings provide.

From: Bolen, Brittany [mailto:bolen.brittany@epa.gov]
Sent: Wednesday, May 3, 2017 6:27 PM
To: David Darling
Cc: Heidi McAuliffe
Subject: RE: Once-in, Always-in rule

Thanks, David. It was a pleasure meeting you, too.

From: David Darling [mailto:ddarling@paint.org]
Sent: Wednesday, May 3, 2017 8:50 AM

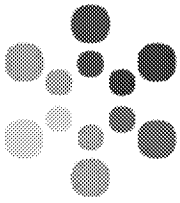
To: Bolen, Brittany <bolen.brittany@epa.gov>
Cc: Heidi McAuliffe <hmcauliffe@paint.org>
Subject: Once-in, Always-in rule

Hi Brittany, it was a pleasure speaking with you yesterday, I wanted to follow-up with the 2007 proposed "once-in always in" policy rule - the citation is 72 Federal Register 69 (January 3, 2007) - docket number EPA-HQ-OAR-2004-0094- here is a link to the rule - https://www3.epa.gov/ttn/atw/gp/fr03ja07.pdf

Best regards,

David Darling

Sent from my iPhone



AmericanCoatings
ASSOCIATION

May 15, 2017

Samantha K. Dravis
Regulatory Reform Officer and Associate Administrator
Office of Policy
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Docket Number EPA-HQ-OA-2017-0190;
Executive Order 13777, Enforcing the Regulatory Reform Agenda

Dear Associate Administrator Dravis:

The American Coatings Association, Inc. (ACA) is a voluntary, nonprofit trade association working to advance the needs of the paint, coatings and adhesives industry and the professionals who work in it. Our membership includes paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA membercompanies collectively produce some 95% of the total dollar volume of architectural paints and industrial coatings in the United States.

ACA member companies operate nearly 1,300 manufacturing facilities, warehouses and distribution centers in all 50 states. More than 275,000 people in the United States are employed in the paint and coatings industry, including those who manufacture, distribute, store, sell, and apply our products. Product shipments by U.S. paint and coatings producers totaled an estimated $28 billion in 2015.

ACA appreciates the opportunity to participate in this regulatory reform effort and provide the agency with the benefit of its experience regarding certain EPA regulations and requirements. We have participated in several of the public meetings, providing information about regulatory requirements that have been costly and problematic for our industry for many, many years.

ACA is hopeful that the regulatory reform effort will allow the agency to take a holistic approach to regulations and modernize requirements with an eye towards synergistic compliance. ACA urges EPA to examine those regulations and requirements that are unnecessary, costly and inconsistent with other requirements and do not further the mission of environmental protection. Below we highlight such requirements and provide cost data along with a specific recommendation for repeal, replacement or modification.

ACA is providing comments on the following regulations and requirements:

1. The 8-Hour Ozone Standard, EPA-HQ-OAR-2008-0699;
2. "Once-in, Always-in" Policy Under National Emissions Standards for Hazardous Air Pollutants for Source Categories;
3. National Volatile Organic Compound Emission Standards for Aerosol Coatings, EPA—HQ—OAR—2006—0971;
4. Triennial Reporting for Aerosol Coatings, EPA—HQ—OAR—2006—0971;
5. TSCA Nanomaterials Reporting Rule, EPA-HQ-OPPT-2010-0572;
6. TSCA, Section 5(e) Consent Orders: Regulation of Chemicals Pending Development of Information During the PMN Process;
7. FIFRA: Requirement to Gain Final Approval for a Reformulated FIFRA-registered Paint Product prior to Distribution or Marketing;
8. FIFRA, Prohibition of Truthful Comparative Information on a Label;
9. FIFRA, Language Requirements for Export Labels;
10. FIFRA, Review of Label Elements upon Application for a Label Amendment;
11. FIFRA, Regulation of Product Claims for Paint Products with Antimicrobial Agents; and
12. EPA Environmentally Preferable Purchasing Program Pilot to Assess Standards and Ecolabels for EPA's Recommendations to Federal Agencies

1. The 8-Hour Ozone Standard, EPA–HQ–OAR–2008–0699

Issue: In October 2015, the National Ozone Standard was lowered from 0.75 ppm to 0.70 ppm.

Implementation of the new standard requires U.S. states to identify whether they are in attainment or in non-attainment by February 2017. Reviewing the ozone standard is a recurring mandate under the Clean Air Act.

Concern: EPA's final rule on the ozone standard is forcing a significant number of states that are currently "in attainment" to "non-attainment" status, triggering a requirement to revise their State Implementation Plans and adopt even stricter volatile organic compound (VOC) emission regulations for coatings. This triggering event is being realized as ozone monitors across the country are demonstrating a marked improvement in air quality under the 2008 standard of 0.75 ppm. Indeed, the previous standard of 0.75 ppm was not yet fully implemented.

Cost to the Coatings Industry: EPA's final stringent ozone standards will limit business expansion in nearly every populated region of the United States. and impair the ability of U.S. companies to create new jobs. EPA's lowered range adds unnecessary red tape for companies seeking to expand even in areas that can attain those standards. Increased costs associated with restrictive and expensive permit requirements will likely deter companies from siting new facilities in a nonattainment area. ACA shares the practical concerns of

manufacturers regarding potential exorbitant costs this regulation would create for the paint and coatings industry without commensurate benefits to public health or the environment. *A study conducted by the National Association of Manufacturers (NAM) and NERA Economic Consulting, estimated this final rule could cost the economy $140 billion per year, result in 1.4 million fewer jobs, and cost the average household $830 per year in the form of lost consumption — making this the "costliest regulation in history" and threatening manufacturing.*

Recommended Solution: ACA urges a two-step solution to this problem: 1) EPA should revert to the 2008 standard of 0.75 ppm and fully implement this standard so that the forward progress already achieved can be extended without unnecessarily burdening the paint and coatings industry with increased standards and costs for many years to come; and 2) EPA should amend the Clean Air Act Regulations to extend the time for review of the ozone standard to every 10 years. Currently the law requires a review every five (5) years. Extending the review of the ozone standard to every 10 years will allow for more stability in the marketplace for formulators while still protecting human health and the environment.

2. **"Once in, Always in" Policy under National Emission Standards for Hazardous Air Pollutants for Source Categories**

This "regulation" is a May 16, 1995 EPA memorandum titled, "Potential to Emit (PTE) for MACT Standards – Guidance on Timing Issues," from John Seitz, Director, Office of Air Quality Planning and Standards (OAQPS), to Regional Air Division Directors — commonly known as the "Once in, Always in" memo — and may be found here: https://www.epa.gov/sites/production/files/2015-08/documents/pteguid.pdf.

Issue: A "major source" is defined as a source that has the potential to emit (PTE) hazardous air pollutants (HAP) up to 10 tons per year (tpy) of any single HAP or 25 tpy of any combination of HAPs. Sources below this threshold are considered "area sources."

Under the "once in, always in" policy, a major source may become an area source (i.e., minor source) by limiting its PTE HAP below the major source thresholds by no later than the first compliance deadline listed under the applicable Maximum Achievable Control Technology (MACT) standard (also referred to as National Emission Standards for Hazardous Air Pollutants or NESHAP). However, a source that fails to achieve "area source status" by the first MACT compliance deadline must remain subject to the MACT *even if it subsequently reduces HAP emissions below major source levels at a later date*. In other words, sources will always be subject to the MACT rules, regardless of whether the source is no longer a major source of HAP.

Note that that EPA published a proposed rule on January 3, 2007 to replace the "once-in always in" policy rule - (docket number EPA-HQ-OAR-2004-0094. https://www3.epa.gov/ttn/atw/gp/fr03ja07.pdf). However, this rulemaking was never finalized.

Concern: The coatings manufacturing industry has substantially reduced the use of HAPs since the 1990s. In fact, many facilities subject to the Miscellaneous Coatings Manufacturing (MCM) and Miscellaneous Organic Chemical Manufacturing MACT (MON) MACTs are now "area source" facilities, but still must comply with the MCM requirements even though they are not major source facilities. While many coating and resin manufacturing operations could reduce emissions prior to the first compliance date of the MCM and MON, other facilities could not. Facilities that could not reduce their emissions have since installed expensive thermal oxidation units.

This guidance is outdated and unnecessary and imposes a substantial burden on industry that well exceeds any benefits. This "policy" or "guidance" has been applied by EPA as a "rule," with binding effects on the regulated community, including very burdensome compliance costs. Industry resources spent on compliance could be used instead for R&D, or modernization activities. This policy also acts as a disincentive for industry, since facilities have no incentive to voluntarily reduce HAP emissions below major source thresholds.

Cost to the Coatings Industry: Thermal oxidation units require a significant capital investment (millions of dollars per facility) and annual operation and maintenance costs (several hundred thousand dollars per facility per year in fuel cost alone). These units consume large amounts of electricity and natural gas, which results in additional emissions of carbon dioxide, nitrogen oxides and carbon monoxide. *EPA has estimated that installation and operating of air pollution controls for the MCM and MON rules would require an overall energy demand increase of 5.83 trillion BTUs; a total capital expenditure of $184 million; yearly operating costs of nearly $91 million; and an increase in NOx, CO, SOx emissions of 987 tons per year.*

Recommended Solution: ACA recommends that EPA withdraw or rescind this policy.

3. **National Volatile Organic Compound Emission Standards for Aerosol Coatings, EPA—HQ—OAR—2006—0971**

Issue: The regulatory landscape for aerosol coatings has historically been relatively simple. There are two primary regulating agencies that govern aerosol coatings: the U.S. EPA and the California Air Resources Board (CARB). In 2008, EPA finalized a national rule for aerosol coatings that largely mirrored CARB's 1999 aerosol coatings regulation. Since EPA's initial rulemaking in 2008, scientific research has resulted in a more accurate mechanism for calculating the

reactivity of specific compounds. As a result, CARB amended its aerosol coatings regulations and updated its reactivity values in 2010. CARB's standards are now more stringent than EPA's standards.

Concern: There are no longer consistent, uniform categories or standards for aerosol coatings throughout the country. EPA's Table of Maximum Incremental Reactivity (MIR) Values are outdated and no longer align with CARB's Table of MIR Values. Thus, a significant compliance challenge exists as there are now two different MIR Values for a single compound: one that needs to be employed for compliance calculations in California and a different one that will apply for the EPA national rule. This has complicated classification, formulation, calculation, and labeling for aerosol coatings manufacturers.

Impact on Industry: The impact of CARB's amendments has been substantial on the aerosol coatings industry because EPA's standards are no longer consistent with CARB's standards. The most pressing concern for aerosol coatings manufacturers is calculating two different values for compliance purposes. The process takes more time, costs more money, and expends more resources. In addition, EPA's outdated standards are stifling innovation and not utilizing the most recent scientific research available. Under EPA's current regulations, it is not worth it for industry members to come up with different formulations using new compounds with lower VOC emissions because the trade-off is having to use a high default value. Overall, the inconsistencies between EPA and CARB's aerosol coatings regulations have created burdens with compliance that is costly for industry.

Recommended Solution: ACA recommends that EPA modify its aerosol coatings regulations by updating the reactivity values in MIR Tables 2A, 2B and 2C, adjusting the default value, amending the regulatory language to allow for changing the value of existing compounds, and adding new compounds to the tables. These slight modifications would align EPA's aerosol coatings regulations with the most recent scientific research available and promote uniformity and consistency throughout the country. ACA is not asking EPA to impose California's regulations across the country; rather, ACA is asking EPA to update its standards and reactivity values. Since EPA's aerosol coatings regulations are originally based on CARB's regulations, this harmonization seems to be natural and practical. Most importantly, it will resolve inconsistencies and reduce burdens and costs on the aerosol coatings industry.

4. **Triennial Reporting for Aerosol Coatings, EPA—HQ—OAR—2006—0971**

Issue: EPA's current aerosol coatings regulations require regulated entities to report certain information to EPA every three years (40 CFR § 59.511(i)). In these triennial reports, aerosol coatings manufacturers must report VOC formulation data, VOC amounts, individual product codes, and other identification information.

Concern and Impact on Industry: These triennial reporting requirements are not only burdensome and costly for aerosol coatings manufacturers, but they also provide little, if any, useful value or information to EPA. This additional reporting requirement costs the industry in time, money, and resources. Plus, if there are compliance issues, this same information can be requested by the Agency and manufacturers would then be required to provide it. So, this additional triennial reporting requirement is unnecessary.

Recommended Solution: ACA urges EPA to eliminate the triennial reporting requirements for aerosol coatings manufacturers. This same information can be requested by EPA at any time should compliance issues arise.

5. **TSCA Nanomaterials Reporting Rule, EPA-HQ-OPPT-2010-0572**

EPA's "Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements - Final Rule" was published on January 12, 2017.

Issue: Our industry consists of downstream processors of emulsions and dyes containing some particles in the nanoscale. These raw materials are used during manufacture to produce a final product with no inhalation risk for nanomaterials. Reporting from such downstream processors is duplicative, unnecessary, and costly

The final EPA "Nanomaterial Reporting" rule requires a one-time report and recordkeeping of existing exposure and health and safety information on nanoscale chemical substances in commerce. This rule requires companies that manufacture, import or process certain chemical substances already in commerce as nanoscale materials to notify EPA of certain information, including specific chemical identity; production volume; methods of manufacture; processing, use, exposure and release information; and available health and safety data. The compliance deadline for this report is August 14, 2018.

Impact on Coatings Industry: The use of emulsion polymers and the milling of pigments during the coating manufacturing process could fall below the 100 nanometers threshold and potentially trigger reporting under the final rule. Emulsion polymers and milling processes have been conducted for decades in the coatings industry and there is minimal opportunity for exposure to the nanoscale material after the film cures. Nanoscale materials which may be incorporated into paint products would not be available since they would be bound in the dry coating film. During the manufacturing process, existing OSHA requirements for engineering controls and PPE adequately control any risks. A requirement to report on these materials would be unnecessary and duplicative. Given the low exposure and low risk of these applications, EPA should exempt these substances from the reporting requirements.

ACA estimates that about 10 to 15 coatings companies would report under this rule. Using a conservative estimate, the reporting requirement alone would cost at least $3.5 million to the coatings industry. These figures are based on EPA estimates and information from ACA member companies. EPA estimates that across all industry sectors, about 823 companies will be affected by this rule, with a distribution of 80/20 of large to small companies.[1] The agency estimates 295 companies will report each year, at 4.7 reportable substances per company.[2] However, this is contrary to the information industry has provided. Companies estimate upwards of 50 reportable substances. EPA estimates each report would take up to 175 hours to complete,[3] at a cost of $10,533 just to complete the form, excluding other related activities.[4] A company with 30 to 50 reportable substances could easily spend $300,000 to $530,000 to comply, bearing in mind some companies will have more than 50 substances to report.

Recommended Solution:
ACA recommends that EPA exempt processors from this reporting requirement. Reporting imposes significant costs on processors and does not provide EPA with new information. Exemption of processors would allow EPA to more effectively gather relevant information by reducing the number of superfluous processor reports.

ACA is also recommending that EPA exempt nanoscale materials that are incorporated into paint products. These processes are known to be low risk and the final product has a low exposure risk because nanoscale materials are encapsulated in a dried paint film. Existing OSHA regulations provide adequate safety standards. The addition of this reporting rule would be overbearing on industry and is duplicative as OSHA requirements address this risk.

ACA also urges EPA to extend the compliance period from one year after the effective date to two years after the effective date. This extension would allow upstream and downstream users of nanomaterials an appropriate amount of time to prepare these reports, which EPA estimated will take 175 hours to complete.

6. TCA, Section 5(e) Consent Orders: Regulation of Chemicals Pending Development of Information During the PMN Process

Under the revised Toxic Substances Control Act (TSCA), EPA must render a determination after considering each Pre-manufacture Notice (PMN) submission. (TSCA, Section 5(a)(3)). Companies expect EPA to increase the number of

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[1] RIN 2070-AJ54, *Economic Analysis for the Final TSCA Section 8(a) Reporting Requirements for Certain Chemical Substances as Nanoscale Materials*, p. 2-8, prepared by: Economic and Policy Analysis Branch; Chemistry, Economics, and Sustainable Strategies Division; Office of Pollution Prevention and Toxics.
[2] *Id.* at p. 2-6
[3] *EPA Nanomaterials Reporting Form*, available at Docket No. EPA-HQ-OPPT-2010-0572 (EPA reporting form estimates 175 hours to complete).
[4] *Id.* at f.n. 1, p. 3-3.

consent orders under Section 5(e), allowing restricted use of a PMN substance after EPA determines information is insufficient for a final determination. A Section 5(e) consent order allows a company to use a chemical while developing information that assists EPA in coming to a final determination. EPA issues complex consent orders with a variety of requirements including:

- Testing requirements for environmental fate and toxicity;
- Personal protective equipment;
- New chemical exposure limits;
- Hazard communication requirements;
- Restrictions on releases to water, air and/or land; and
- Recordkeeping.

These requirements are detailed in consent orders that are often more than 70 pages.
ACA supports EPA's efforts to expeditiously evaluate the current backlog of PMN submissions and control risks with consent orders while companies develop test data. EPA can reduce duplicative and excessive requirements in consent orders while maintaining the same degree of protection to public health and the environment.

With revisions to TSCA, EPA will now issue an interim consent order or a final determination for every PMN filed by a company – compounding costs and administrative difficulties associated with compliance. Requirements in consent orders often address issues covered under other EPA programs or OSHA requirements. Industry is burdened with developing a secondary compliance program for consent orders. Requirements in consent orders may also vary from requirements in other programs, creating a patchwork of compliance obligations and sometimes irregular compliance dates, as explained below.

Such requirements do not advance protections to public health or the environment, but increase the regulatory burden and associated costs to industry. Companies that remain committed to environmental responsibility find certain requirements in consent orders unnecessary and burdensome. One such company maintains a staff of five of employees devoted to product compliance full time at the corporate level, with 75% of time devoted to TSCA compliance. At the facility level, one employee at each facility devotes about 10% of their time to TSCA compliance activities. This company estimates at least 11760 hours per year devoted to TSCA compliance. Reduction in duplicative and inconsistent requirements in consent orders would reduce the administrative burden on such companies.

ACA suggests the following improvements:

- Reduce the number of requirements imposed in consent orders by referencing other statutory programs where an issue is already covered. Water discharges could be regulated through National Pollutant Discharge Elimination System (NPDES) permits or Resource Conservation and Recovery Act (RCRA) requirements rather than a restriction in a Section 5(e) consent order.
- EPA could repeal duplicative EPA hazard communication and burdensome PPE testing requirements while maintaining references to OSHA hazard communication and PPE requirements in consent orders.
- EPA could also stop requiring reporting of production and/or processing volumes while companies develop test data required in consent orders.

Additional details are included below:

a. Limits to discharges into waterways

Issue: Restrictions on effluent discharges in consent orders may duplicate or sometimes impose additional restrictions not included in a facility's NPDES permit, although the chemical at issue does not pose an eco-toxicological risk. To comply, companies must implement new control and monitoring systems, beyond those used to comply with NPDES requirements. Although an NPDES permit may not cover discharges from new pollutants, NPDES permits restrict overall percent nitrogen and phosphorous discharged, including contributions from new pollutants. Hazardous waste requirements under RCRA require containment and disposal of effluent discharge with new chemicals where appropriate.

Concern: Limits to discharge in consent orders do not enhance protections to environment and public health while imposing significant costs to industry. These restrictions are interim measures while companies submit additional eco-toxicological data. Similar protections are included in a facility's NPDES permit or through RCRA requirements.

Impact/Cost to the Coatings Industry: Companies can incur significant costs with little to no additional protection to public health or the environment. One company reports additional costs of $600,000 per year to comply with discharge requirements in just one order. This estimate does not include employee hours. Costs are compounded since companies are now subject to multiple consent orders. One company reports that it anticipates about 40 consent orders where it previously only had to comply with one or two orders per year.

Recommended Solution: ACA recommends that EPA issue consent orders that reference NPDES permit requirements and RCRA requirements without imposing additional restrictions to discharge. EPA should also rescind existing discharge requirements in consent orders currently in effect.

b. Hazard Communication standards (HCS) in consent orders

Issue: Human health hazard and precautionary statements required on safety data sheets for PMN substances are not aligned with OSHA's HCS. Consent orders typically replicate hazard communication specified for chemicals subject to SNURs at 40 CFR 721.72(g) and (h). In addition to health hazard and precautionary statements, consent orders include basic information that must appear on SDS and labels, such as manufacturer's identity, exposure levels and chemical identity. Although EPA largely replicates OSHA's SDS and labeling requirements, requirements are not identical, placing companies in a tenuous position by requiring compliance evaluations under both EPA and OSHA requirements.

Concern:
ACA believes that the human health hazard and precautionary statements prescribed in consent orders pose duplicative and unnecessary burdens on the coatings industry and create confusion among the workers. Given that the intention of these requirements is to communicate hazards to employees, providing similar hazard statements to employees in two different verbiages (HCS statements vs EPA statements) creates unnecessary complexity for employers and simply confuses workers. EPA's data requirements for SDS add another layer of complexity, requiring companies to check for compliance with both EPA and OSHA data requirements.

Impact to the Coatings Industry:
Our members must develop two compliance systems for hazard communication requirements, while evaluating differences and similarities of both systems to comply. This seemingly benign dual hazard communication system has aggregate impacts for management. Written hazard communication programs must be aligned with EPA and OSHA requirements. Companies must also align management systems, train workers, and correct SDS and labels as necessary to comply.

Recommended Solution:
ACA recommends that EPA minimize hazard communication requirements in consent orders to those relevant to environmental hazards (not covered by OSHA); and that EPAinclude one sentence requiring compliance with OSHA's HCS for all other requirements.

c. PPE testing requirement in consent orders

Issue: Consent orders adopt two standards related to permeation tests for PPE not required by OSHA: 1) ASTM F739, "Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact," and 2) ASTM F1194-99(2010), "Standard Guide for Documenting the Results of Chemical Permeation Testing of Materials Used in Protective Clothing Materials." Companies must test and maintain records as specified in these standards.

Concern: EPA creates a secondary permeability assessment that may vary from a company's current testing practice for compliance with OSHA's requirement. EPA's testing standards may not be the most current or effective test methods. In contrast to EPA's requirement, OSHA's PPE maintenance requirement gives companies flexibility in implementing appropriate and current tests.

Impact / Cost to the Coatings Industry: Companies must modify policies and practices designed for OSHA compliance to meet EPA testing requirements. The costs of EPA-specified tests are in the range of $5,000-$10,000.

Recommended Solution: ACA recommends that EPA modify consent order language to delete references to permeability testing standards while maintaining reference to OSHA requirements for PPE at 29 CFR 1910.38 (hand protection) and 29 CFR 1910.133 (eye and face protection).

d. Volume reporting in consent orders

Issue: Consent orders require companies to report cumulative manufacture volumes every six months from the date of commencing manufacture, while developing test data. Reports must be submitted every six months until the PMN submitter develops final submission of test data.

Concern: This reporting requirements is of marginal use to EPA, but imposes administrative costs on industry. Moreover, the requirement causes staggered reporting dates that can be difficult to track when attempting to comply with several consent orders. EPA presumably uses data to enforce production limits for PMN substances, but other methods of reporting could achieve the same result.

Impact/Cost to the Coatings Industry: Administrative costs to industry can be significant when tracking compliance dates and drafting multiple reports. This burden is compounded by irregular compliance dates set every six months from the date of manufacture of each PMN substance.

Recommended Solution: ACA recommends that EPA repeal this requirement. Reported information is of little to no value to EPA, but significantly adds to a company's administrative burden. EPA could require a one-time submission of production volumes with final test data, once developed. In the interim, companies could report to EPA, if they exceed production limits or anticipate excess manufacture. At a minimum, EPA should require annual volume reporting at one set time during the year, instead of requiring reporting every six months from the date of manufacture.

7. **FIFRA: Requirement to gain final approval for a reformulated FIFRA registered paint product prior to distribution or marketing**

Issue: Paint and coatings manufacturers sometimes modify a FIFRA registered paint product with an active ingredient registered under FIFRA, triggering an application for amended registration under 40 CFR 152.44. Product reformulation does not alter the active ingredient. Coatings manufacturers must obtain EPA approval prior to marketing or distributing the reformulated product, potentially leading to delays or temporary withdrawal from market, pending final approval.

Concern: EPA has already deemed the active ingredient in the reformulated product as safe for the use at issue. Requiring prior approval inhibits innovation and delays bringing new formulations to market.

Impact on the Coatings Industry: ACA member companies can lose profits from delays in bringing a reformulated product to market while waiting for final approval.

Recommended Solution: ACA recommends that after submitting an application for amended registration, but prior to final approval, EPA allow formulators to market or distribute a reformulated product that is substantially similar to an existing FIFRA registered paint product. EPA can implement this change by amending language in 40 CFR 152.44.

8. **FIFRA - Prohibition of Truthful Comparative Information on a Label**

Issue: FIFRA prohibits the sale of misbranded pesticides (FIFRA Section 12(1)(E)), including pesticides with labels that are "false or misleading in any particular" (FIFRA Section 2(q)(1)(A)). FIFRA details its prohibition on false or misleading claims on labels at 40 CFR 156.10(a)(5) with specific examples, including, "A false or misleading comparison with other pesticides or devices..." In practice, EPA interprets this section to refuse approval of labels with truthful, non-misleading claims on a proposed label.

Concern: Manufacturers of FIFRA-registered paint products and non-registered paint products containing antimicrobials are barred from providing accurate information about their product, due to EPA's broad interpretation of "false or

misleading" claims. Paint and coatings manufacturers carefully formulate products with antimicrobials to optimize performance. Accurate comparative information on a label can assist buyers in purchasing a paint product that best meets their needs. Comparative statements also encourage competition and drive down product costs. Moreover, the prohibition of "false or misleading" claims under FIFRA is duplicative of Section 5 in the Federal Trade Commission Act prohibiting unfair or deceptive practices.

Cost to the Coatings Industry: Paint and coatings companies may not be maximizing market share for certain high-performance products because, in practice, EPA prohibits even truthful comparative information on labels of paints and coatings containing antimicrobials.

Recommended Solution: ACA recommends that EPA modify language in 40 CFR 156.10(a)(5)(ix) and (x), currently prohibiting safety claims in general to prohibit only "false or misleading" safety claims, thereby allowing legitimate safety claims and comparative statements. EPA should also generate guidance for industry and EPA staff encouraging truthful statements in labels while discouraging EPA staff from misinterpreting FIFRA prohibitions against false and misleading statements to prohibit truthful comparison claims.

9. FIFRA - Language Requirements for Export Labels

Issue: EPA requires that pesticides prepared for export include a label on the immediate product container in multiple languages — namely, in English — the language of the country of destination, and the official language of the importing country. (40 CFR 168.69(c)). To place a product in a foreign market, exporters must comply with domestic labelling laws of the foreign country, including language requirements. In effect, EPA's language requirement is burdensome and unnecessary, requiring compliance with a U.S. label requirement for products placed in foreign markets.

Concern: EPA's requirement creates an unnecessary labeling requirement that can significantly increase costs when EPA requires a label in a language not required by the product's destination country. EPA's requirement also creates an additional administrative burden to evaluate compliance.

Cost to the Coatings Industry: Companies may be forced to design, print and place multi-language labels on a product. Associated costs can be significant.

Recommended Solution: ACA recommends that EPA repeal 40 CFR 168.69(c) in its entirety.

10. FIFRA - Review of Label Elements upon Application for a Label Amendment

Issue: Amendments to labels of FIFRA-registered products, including FIFRA-registered paint products, require an application under section 40 CFR 152.108. EPA review of applications often results in EPA re-evaluating and requiring changes to label elements that it had previously approved, beyond the text of the requested amendment. These changes are due to shifts or evolution of EPA policy or practice regarding existing claims made on the label.

Concern: Upon application to amend a label, a paint or coatings manufacturer may be disadvantaged in the marketplace when EPA requires a change to previously approved label elements beyond the requested amendment when competitors are not required to change labels at the same time. EPA's approach creates an unlevel playing field by reopening review of settled label elements only for an applicant seeking an amended label.

Cost to the Paint and Coatings Industry: Paint and coatings manufacturers may lose market share due to varying label requirements.

Recommended Solution: ACA recommends that during review of an application for an amended label, EPA should reserve any issues with previously approved label elements, beyond the requested amendment, for a separate process, while focusing evaluation of the application on requested amendments. EPA should then require all registrants comply at the same time with any decisions about the reserved label elements. To require this approach, EPA can amend text of 40 CFR § 152.108 to require a separate proceeding when it initiates changes to label elements not proposed by the applicant.

11. FIFRA - Regulation of Product Claims for Paint Products with Antimicrobial Agents

Issue: Under an exemption to FIFRA registration requirements at 40 CFR §152.25, articles — including paints and coatings — containing antimicrobial pesticides are not subject to registration when the antimicrobial agent is used to protect the article itself and any related claims on the label relate to protection of the article, rather than any benefit to the user. However, where a product label includes claims that antimicrobial agents used to treat the article may also benefit the user, a manufacturer must register the paint or coating as a pesticide.

Concern: A paint or coating treated with an antimicrobial agent reduces bacterial contamination in the paint or coating itself. The antimicrobial agent prevents contamination since water is a highly sensitive breeding ground for bacterial growth; minimizes additional transportation and refrigeration during the distribution stage; and increases the products' lifespan and minimizes waste. In addition, the antimicrobial agent may also provide an ancillary public health benefit. Yet, manufacturers that wish to indicate any ancillary public health benefit on a label are required to register their paint or coating product as a

pesticide. Registration can be costly and time consuming while adding a disincentive for manufacturers to reformulate products containing antibacterial agents, thereby stifling innovation.

Cost to the Paint and Coatings Industry: Paint and coatings manufacturers may not be maximizing market share by failing to fully describe benefits of paints containing antimicrobial agents, without registering the paint or coating as a pesticide.

Recommended Solution: EPA should create a list of standard approved phrases for use with articles treated with specified antimicrobials. This approach would provide truthful public health claims for articles treated with antimicrobials where the article might have some ancillary public health benefit, but that benefit is not the main purpose of using the antimicrobial agent. This approach would also relieve manufacturers from registering articles whose main function is not as a pesticide, thereby conserving both agency and manufacturer resources.

12. EPA Environmentally Preferable Purchasing Program Pilot to Assess Standards and Ecolabels for EPA's Recommendations to Federal Agencies

Issue: Executive Order 13693 directed the U.S. Government to specify federal standards and ecolabels, such as Energy Star, WaterSense, and Safer Choice -- labels that identify products meeting strict federal standards for energy efficiency, water efficiency, and safer chemicals. EPA developed "Guidelines for the Assessment of Environmental Performance Standards and Ecolabels for Federal Procurement" to create a "transparent, fair, and consistent approach to selecting environmental performance standards and ecolabels to support the agency's mission and federal sustainable acquisition mandates." The guidelines were developed and piloted with participation and comments from multiple stakeholders, including industry, and finalized in December 2016.

Concern: ACA supports the stated goals of the pilot, "to create a transparent, fair, and consistent approach to selecting environmental performance standards and ecolabels that support the Agency's mission and federal environmentally preferable purchasing mandates." However, ACA is concerned that major changes were made to the guidance document after the public comment period closed and without participation and feedback from the interested and impacted participants on the paint panel. While the results of the pilot indicate that many Standards Development Organizations (SDOs) could not comply with certain criteria, we understood that those criteria would signal the SDO community to improve their standards in the future. Instead, it appears that where the SDOs were unable to achieve critical criteria, such as open, transparent stakeholder involvement in standard development, the bar has been lowered to allow for closed door, arbitrary standard development.

Impact on the Coatings Industry: By requiring select standards or certification for products specified and purchased by the federal government industry must expend time and money to achieve or certify products to these multiple, and in some cases, arbitrary standards and ecolabels.

Recommended Solution: ACA recommends that EPA consider abandoning the guidelines or amendments to provide manufacturers flexibility to accommodate the variety of approaches to and types of standards and ecolabels that exist in the marketplace today.

Conclusion

ACA is encouraged by EPA's efforts to solicit the opinions and comments from affected parties. Our members are constantly working to understand and comply with the environmental requirements imposed by the agency and are pleased to see this Administration undertake such a comprehensive effort. We believe that there is a significant number of modifications and changes that can be made to some of the regulations that will streamline compliance efforts without jeopardizing the environment or the health and safety of customers, employees and the public. We have provided twelve (12) examples of regulations that are ineffective, outdated and inconsistent with other more relevant requirements. Regulatory reform is desperately needed to ensure a competitive and sustainable coatings industry.

Thank you for the opportunity to submit comments on this very important matter; we look forward to talking with you further about efforts to modernize these specific requirements.

If I may answer questions or provide additional information, please do not hesitate to contact me at 202.719.3686 or hmcauliffe@paint.org.

Respectfully submitted,

Heidi K. McAuliffe
Vice President, Government Affairs

Courtesy Copies:

Sarah Rees, US EPA, Office of Policy
Brittany Bolen, US EPA, Office of Policy

Keith Barnett, US EPA, Office of Air and Radiation
Kim Teal, US, EPA, Office of Air and Radiation
Kaye Whitfield, US EPA, Office of Air and Radiation

Message

From: Robert Helminiak [helminiakr@socma.com]
Sent: 8/8/2018 3:00:23 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Meeting Follow Up

Hi Brittany,

I just wanted to follow up on our 7/25 meeting.

I touched on three items, but did not go into great detail, and wanted to follow up and make sure they are on your radar.

1. RCRA Exemption – SOCMA members have recently had inspections in which a standard exemption, 40 CFR §261.4(c), is not being accepted. It has been in place for over 20 years and this is the first time EPA has ever not granted the exemption. We are working on this with Elizabeth Corona who is developing a one page brief for you.

2. DSW – California Communities Against Toxics v. EPA – SOCMA is intervening in support of EPA – CCAT is suing over the May 20, 2018 DSW rule "Response to Vacatur of Certain Provisions of the Definition of Solid Waste Rule" 83 Fed. Reg. 24,664.

3. RMP – This is by far the simplest. We strongly support the proposed rule. We will file comments and do anything else we can to support the proposed rule becoming the final rule.

I am happy to provide you with more information on all three topics. If there is anything I can do to help move these issues along (or support your efforts) please let me know.

Regards,
Robby

SOCMA
Society of Chemical Manufacturers & Affiliates

Robert Helminiak
Vice President, Legal & Government Relations • SOCMA

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Message

From: Heidi McAuliffe [hmcauliffe@paint.org]
Sent: 3/22/2018 11:18:47 PM
To: Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]
CC: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Thank you and ACA's Petition for Rulemaking
Attachments: (3) ACA Second Petition to Add Compounds to EPA's Aerosol Coatings Tables (002).pdf

Flag: Follow up

Samantha,

Thank you for responding to all of the questions posed to you during the association roundtable earlier this month. I always learn quite a bit from the whole discussion. It was very generous of you, and Brittany, to give us so much time to explore our issues.

I wanted to follow up with you regarding ACA's petition for rulemaking which seeks to add compounds to the Reactivity Table in the aerosol coatings regulation. I realize that my very short presentation at the roundtable may have raised more questions than I answered. I have attached the most recent petition filed by ACA in July of 2017.

We had originally drafted a more complex petition, requesting changes to the standards as well as additional product categories. On the advice of EPA, we pared down the requested changes and focused on the more narrow issue of adding compounds to the table. This was done to facilitate more efficient handling by EPA and our hope was that a direct final rule would be pursued. We have been told recently, however, that other priorities will supercede any action at all on our petition.

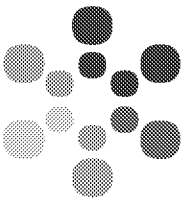
I would like to talk with you further about the aerosol coatings regulation. I know that there are some restrictions on moving forward with a regulation due to the "2 for 1" requirement but there are good opportunities in this rule to eliminate a burdensome requirement which could help facilitate action.

Please feel free to give me a call at your leisure or drop me an email. I am happy to talk with you more about this issue. As always, thank you for your assistance.

Best regards,

Heidi K. McAuliffe ▪ American Coatings Association ▪ Vice President, Government Affairs
202- 719-3686 | Ex. 6 (m) | 202-263-1102 (fax) | hmcauliffe@paint.org | www.paint.org

901 New York Ave. NW, Suite 300 West ▪ Washington, DC 20001
Coatings protect. Coatings preserve. Coatings provide.



American Coatings ASSOCIATION℠

July 27, 2017

Ms. Kaye Whitfield
U.S. Environmental Protection Agency (EPA)
Office of Air Quality Planning and Standards
109 T.W. Alexander Drive
Research Triangle Park, NC 27707

RE: ACA Petition to EPA to Add Compounds to Table 2A of the National Volatile Organic Compound Emission Standards for Aerosol Coatings

The American Coatings Association (ACA)[1], whose members consist of entities that are regulated under 40 CFR Part 59, Subpart E, hereby petitions US EPA to add several compounds to Table 2A of the National Volatile Organic Compound Emission Standards for Aerosol Coatings.

Under 40 CFR § 59.511(j), a regulated entity may petition the Administrator to add to EPA's Aerosol Coatings Tables any compounds needed for an aerosol formulation that are not listed in those tables. Petitions must include the "chemical name, CAS number, a statement certifying the intent to use the compound in an aerosol coatings product, and adequate information for the Administrator to evaluate the reactivity of the compound and assign a RF value consistent with the values for the other compounds listed in Table 2A."[2]

After reviewing EPA's Tables, various aerosol coatings manufacturers subject to EPA's regulations concluded that several compounds are being used by formulators that are not yet on EPA's Tables 2A, 2B, or 2C. It is the intent of industry members and the regulated community to use these compounds in aerosol coatings products moving forward.

Furthermore, the reactivity factors of each of the compounds have undergone significant scientific study under the direction of Dr. William P.L. Carter and have been peer reviewed by the scientific community.[3] Dr. Carter's reports reflect the most up-to-date scientific research available and are widely accepted. His research is also the basis for California Air Resources Board's (CARB) Aerosol Coatings Regulations, which has also assigned Maximum Incremental Reactivity (MIR) Values to these compounds.[4]

---

[1] The American Coatings Association (ACA) is a voluntary, nonprofit trade association working to advance the needs of the paint and coatings industry and the professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals. ACA serves as an advocate and ally for members on legislative, regulatory, and judicial issues, and provides forums for the advancement and promotion of the industry through educational and professional development services.

[2] 40 CFR § 59.511(j). https://www.ecfr.gov/cgi-bin/text-idx?SID=dcbfa03c404c58a04e4ca497c12d13a0&mc=true&node=se40.6.59_1511&rgn=div8.

[3] Dr. William P.L. Carter's 2009a Report: https://www.arb.ca.gov/research/reactivity/mir09.pdf.
Dr. Carter's Investigation of Atmospheric Ozone Impacts of Trans-1-Chloro-3,3,3-Trifluoropropene: http://www.cert.ucr.edu/~carter/pubs/ZDErept.pdf.

[4] Title 17, California Code of Regulations, Division 3, Chapter 1, Subchapter 8.6, Article 1, § 94700, et seq. https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I71C45BF0D60811DE88AEDDE29ED1DC0A&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default).

Since the reactivity factors of the following compounds have been studied, peer reviewed, and accepted, and these compounds are intended to be used by the regulated community moving forward, ACA petitions US EPA to add them to Table 2A:

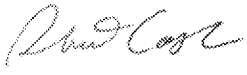
#	Chemical Name	CAS No.	MIR Value
1	Dipropylene Glycol Monomethyl Ether	34590-94-8	2.70
2	2-Nitropropane	79-46-9	0.11*
3	Dibutyl Phthalate	84-74-2	1.25*
4	Dipropylene Glycol Methyl Ether Acetate Isomers	88917-22-0	1.49
5	n-Pentyl Propionate	624-54-4	0.79
6	Dimethoxy Methane	109-87-5	1.04
7	trans-1,2-Dichloroethene	156-60-5	0.81
8	2-Methyl-1-Butyl Acetate	624-41-9	1.17
9	3-Methyl-Butyl Acetate	123-92-2	1.18
10	Benzyl Alcohol	100-51-6	5.11*
11	trans-1,3,3,3,-tetrafluoropropene (HFO-1234ze)	1645-83-6	0.10**
12	trans-1-chloro-3,3,3-trifluoropropene (HFO-1233zd)	102687-65-0	0.04**
13	2,2,4-trimethyl-1,3-pentanediol diisobutyrate	6846-50-0	0.38*
14	Diethyl Phthalate	84-66-2	1.62*
15	Tert-butyl benzene	98-06-6	1.89
16	2-Ethyl-1,3-hexanediol	94-96-2	2.62

* These five new compounds did not have an MIR Value assigned to them at the time that EPA promulgated its aerosol coatings regulation. Thus, the MIR values listed above derive from Dr. Carter's most recent scientific research.

** Please note that both trans-1,3,3,3,-tetrafluoropropene (HFO-1234ze) and trans-1-chloro-3,3,3-trifluoropropene (HFO-1233zd) are both considered "exempt" from the definition of "volatile organic compound" by EPA because of their negligible photochemical reactivity.[5] However, paragraph (s)(7) makes it clear that there are no "exempt" compounds in the aerosol coatings regulation.

Thank you for your consideration of ACA's petition. Please do not hesitate to contact us if you have any questions or concerns.

Sincerely,



Rhett Cash
Counsel, Government Affairs

Raleigh Davis
Assistant Director, Environmental Health and Safety

[5] 40 CFR § 51.100(s)(1). https://www.ecfr.gov/cgi-bin/text-idx?SID=4b2f372b3810358338764680702Ofc18&mc=true&node=se40.2.51_1100&rgn=div8.

Message

From: Burhop, Anna [anna.burhop@bracewell.com]
Sent: 1/22/2018 9:15:08 PM
To: Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
CC: Krenik, Edward [edward.krenik@bracewell.com]; Lee, John [john.lee@bracewell.com]
Subject: RE: Chloroprene RfC
Attachments: ldh-tumor-registry-sjbp-2004-2013.pdf; 110_CD Paper 1_Marsh et al_Chem-Biol Int_2006.pdf; 111_CD Paper 2_Marsh et al_Chem-Biol Int_2006.pdf; HHRG-115-SY18-Wstate-MundtK-20170906.pdf

Thanks again for meeting with us last week. Here's some additional information that you asked for during the meeting: the tumor registry data; the 2007 Marsh study describing cancer mortality rates from several plants, including this one (in two parts); and testimony before House SST on the IRIS program and the bad science underpinning the chloroprene assessment specifically.
Let us know if you have any questions!
-Anna

Tract #	Population	% of St. John Total	NATA Cancer Risk	Risk Rank in US
701	2,685	6%	100.426	119
702	7,323	16%	129.680	22
703	6,258	14%	184.736	7
704	4,381	10%	206.649	5
705	6,229	14%	367.927	3
706	2,810	6%	100.668	116
707	4,348	9%	290.549	4
708	2,537	6%	826.309	1
709	3,115	7%	473.139	2
710	2,840	6%	148.656	15
711	3,398	7%	160.621	9

Total Population of St. John:	45924		
St. John cancer rate (2014):	463.2	per	100000
Louisiana cancer rate (2014):	478.7	per	100000
US cancer rate (2014):	443.6	per	100000

DPE is located here

Data from:
https://statecancerprofiles.cancer.gov/incidencerates/index.php?stateFIPS=22&cancer=001&race=00&sex=0&age=001&type=incd&sortVariableName=rate&sortOrder=default#results

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From: Burhop, Anna
Sent: Tuesday, January 9, 2018 2:17 PM
To: Dravis, Samantha <dravis.samantha@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>
Cc: Krenik, Edward <edward.krenik@bracewell.com>; Lee, John <john.lee@bracewell.com>
Subject: Chloroprene RfC

Samantha and Brittany,

Since joining Bracewell, I have been working on a Request for Correction of the 2010 IRIS Review of Chloroprene. The IRIS Review contains errors and flawed science. We have met with ORD and the Office of the Administrator on this, and would like to brief you both on this as well. Do y'all have some time later this week or next for my colleagues, Ed Krenik and John Lee, and I to come meet with you?

Attached is the letter DPE sent to Administrator Pruitt last June explaining the request. I am also happy to share the full RfC with you.

Please let me know what times may work for your schedule. Feel free to give me a call if you have questions at 202.828.1728

Thank you!

Anna

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Chemico-Biological Interactions xxx (2006) xxx–xxx
Chemico-Biological Interactions
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Mortality patterns among industrial workers exposed to chloroprene and other substances I. General mortality patterns

Gary M. Marsh [a,*], Ada O. Youk [a], Jeanine M. Buchanich [a], Michael Cunningham [a], Nurtan A. Esmen [b], Thomas A. Hall [c], Margaret L. Phillips [c]

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[b] *Occupational and Environmental Health Sciences, School of Public Health, University of Illinois at Chicago, 2121 West Taylor Street, Chicago, IL 60622, USA*
[c] *University of Oklahoma Health Sciences Center, 801 NE 13th Street, CHB 413, Oklahoma City, OK 73190, USA*

Abstract

We conducted an historical cohort study to investigate the mortality experience of industrial workers potentially exposed to chloroprene (CD) and other substances, including vinyl chloride (VC), with emphasis on cancer mortality, including respiratory system (RSC) and liver. In 1999, the International Agency for Research on Cancer (IARC) classified CD as a possible carcinogen (Group 2B); VC was classified in 1987 as a known human carcinogen (Group 1).

Subjects were 12,430 workers ever employed at one of two U.S. industrial sites (Louisville, KY ($n=5507$) and Pontchartrain, LA ($n=1357$)) or two European sites (Maydown, Northern Ireland ($n=4849$) and Grenoble, France ($n=717$)), with earliest CD production dates ranging from 1942 (L) to 1969 (P). Two sites (L and M) synthesized CD with the acetylene process that produced VC exposures. We determined vital status through 2000 for 95% of subjects and cause of death for 95% of the deaths. Historical exposures for individual workers were estimated quantitatively for CD and VC. Workers ever exposed to CD ranged from 92.3% (M) to 100% (G); to VC from 5.5% (M) to 22.7% (L). We computed standardized mortality ratios (SMRs) (using national and regional standard populations) in relation to selected demographic, work history and exposure factors. We used worker pay type (white or blue collar) as a rough surrogate for lifetime smoking history.

For the combined cohort, SMRs (95% CIs) for all causes combined, all cancers combined, RSC and liver cancer were, respectively, 0.72 (0.69–0.74), 0.73 (0.68–0.78), 0.75 (0.67–0.84) and 0.72 (0.43–1.13). Site-specific (L, M, P and G, respectively) SMRs were: for all cancers combined: 0.75 (0.69–0.80), 0.68 (0.56–0.80), 0.68 (0.47–0.95) and 0.59 (0.36–0.91); for RSC: 0.75 (0.66–0.85), 0.79 (0.58–1.05), 0.62 (0.32–1.09) and 0.85 (0.41–1.56); for liver cancer: 0.90 (0.53–1.44) (17 deaths), 0.24 (0.01–1.34) (1 death), 0.0 (0–2.39) (no deaths) and 0.56 (0.01–3.12) (1 death). Among all workers ever exposed to CD, SMRs were: for all cancers combined: 0.71 (0.66–0.76); for RSC: 0.75 (0.67–0.84); for liver cancer: 0.71 (0.42–1.14). We also observed no increased mortality risks among cohort subgroups defined by race, gender, worker pay type, worker service type (short/long term), time period, year of hire, age at hire, duration of employment, the time since first employment, and CD or VC exposure status (never/ever exposed).

In summary, our study has many strengths and is the most definitive study of the human carcinogenic potential of exposure to CD conducted to date. We conclude that persons exposed to chloroprene or vinyl chloride at the levels encountered in the four study sites did not have elevated risks of mortality from any of the causes of death examined, including all cancers combined and lung and

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0009-2797/$ – see front matter
doi:10.1016/j.cbi.2006.08.011

liver cancer, the cancer sites of *a priori* interest. This conclusion is corroborated by our detailed analyses of mortality in relation to qualitative and quantitative exposures to CD and VC at each of the four study sites, reported in our companion paper (Marsh et al., submitted for publication).

Keywords: Chloroprene; Vinyl chloride; Cohort study; Liver cancer; Lung cancer; Mortality

1. Introduction

Chloroprene (2-chloro-1,3-butadiene) (CD) is a monomer used almost exclusively for the production of synthetic rubber and latexes [1]. Epidemiologic studies of CD were stimulated by reports of angiosarcoma of the liver among vinyl chloride (VC) workers [2], a case report of a liver angiosarcoma among a worker exposed to CD but not to VC [3] and the structural similarity between CD and VC.

The earliest CD studies appeared in the Russian literature as case series studies of lung [4] and skin [5] cancers among workers with high exposure to CD. The first informative epidemiological study of CD exposed workers in the U.S. was conducted by Pell [6], who studied an historical cohort of DuPont Chemical Co. workers from two polychloroprene manufacturing plants, including the Louisville, KY plant in the current study. Pell found no consistent evidence of elevated mortality rates or cancer incidence rates among CD-exposed workers. Later cohort studies of CD production workers in China [7] and Armenia [8], and of shoe manufacturing workers in Russia [9] reported excesses in liver cancer among workers exposed to CD. Zaridze et al. [10] performed additional analyses of the Russian and Armenian cohorts that supported the liver cancer findings. The most recent cohort study of cancer incidence among chloroprene production workers in France found no excess in liver cancer, but limited evidence of a lung cancer excess associated with duration of employment [11].

Chloroprene was first evaluated by the International Agency for Research on Cancer (IARC) in 1978 as Group 3 (not classifiable as to its carcinogenicity to humans), and remained in Group 3 following the 1987 reevaluation [12,13]. On the basis of new bioassays that provided sufficient evidence of carcinogenicity in rats and mice [14,15], IARC reclassified chloroprene in 1999 from Group 3, to Group 2B (possibly carcinogenic to humans) [16]. The 1999 reevaluation considered only two epidemiology studies [6,9] whose evidence was deemed inadequate.

To provide more definitive epidemiological evidence regarding the long-term health effects of exposure to CD, a four-plant, multi-national epidemiologic study of workers with potential exposure to CD was commissioned in 1999 by the International Institute of Synthetic Rubber Producers (IISRP). The exposure assessment component of the study was conducted at the University of Oklahoma (UOk) and the University of Illinois at Chicago (UIC); the epidemiology and biostatistics component was conducted at the University of Pittsburgh (UPitt).

We report here the results of our analysis of general mortality patterns among the CD cohort. Detailed accounts of the historical exposure reconstruction and the results of our analyses of mortality in relation to CD exposure are presented elsewhere [17–21].

2. Methods

2.1. Study sites and subjects

The chloroprene (CD) cohort included all workers ($n = 12{,}430$) with potential CD exposure at any of four CD production sites from plant start-up date through the end of 2000 (1999 for one site). The sites include two DuPont/Dow Elastomers LLC (DDE) plants in the U.S. (Louisville, KY and Pontchartrain, LA), one DDE plant in Maydown, Northern Ireland (NI) and one Enichem Elastomers France plant in Grenoble, France (FR) (called here Plants L, P, M and G). CD production dates for each plant were: L (1942–1972), P (1969–date), M (1960–1998) and G (1966–date). In two Plants (L and M), CD production included an acetylene-based process that produced vinyl chloride (VC) as a by-product. Plant L made CD only through the acetylene process that was phased out between 1971 and 1976; Plant M made CD by the acetylene process from 1960 to 1980 then only by the butadiene process from 1980 to 1998. Plants P and G used only the butadiene process to produce CD. The newer butadiene process did not involve VC exposures and resulted in lower CD exposures for jobs related to monomer production than those associated with the early production years of the older Plants L and M. Details of the history, processes and chemical exposures associated with each study plant is described elsewhere [17–21].

With the exception of Plant G, the study population was enumerated from computerized employee databases

Please cite this article as: Gary M. Marsh et al., Mortality patterns among industrial workers exposed to chloroprene and other substances, Chemico-Biological Interactions (2006), doi:10.1016/j.cbi.2006.08.011

Table 1
Key features of cohort study design

Characteristic	Louisville, KY	Maydown, NI	Pontchartrain, LA	Grenoble, FR	All plants
Subjects	5507	4849	1357	717	12,430
Person-years	197,919	127,036	30,660	17,057	372,672
Earliest hire date	1942	1947	1962	1966	–
CD production dates	1942–1972[a]	1960–1998	1969–date	1966–date	–
CD production process	Acetylene	Butadiene and acetylene	Butadiene	Butadiene	–
Observation period	1949–2000[b]	1960–2000	1962–2000	1966–1999[c]	–
Maximum observation period through 2000	52 years	41 years	39 years	34 years	–

[a] Monomer production ended in 1972, CD currently in use at plant.
[b] Dates chosen to avoid fifth revision of International Classification of Diseases (ICD).
[c] Follow-up through 1999 only.

and by manual review of hard copy personnel records. We verified the completeness of the cohorts for all but Plant G by cross checking names among the various data sources, including the corporate mortality registry and earlier cohort study files of Plant L and Plant P held by the DuPont Chemical Company. For Plant P, we identified but could not locate, the records of 191 employees who had transferred to other DDE sites; however, these were mostly salaried workers with little potential for CD exposure. Eighteen potential subjects from Plant M chose not to participate in the study. The Plant G cohort was enumerated and verified by French investigators as an expansion and update of their earlier cohort study of cancer incidence [11].

The total CD cohort includes 12,430 subjects who contributed 372,672 person-years of observation, with Plants L and M comprising the bulk of the subjects and person-years (Table 1). Plant L is the oldest and largest with CD production dates extending back to 1942. With the exception of Plant L, study periods roughly coincided with CD production dates and ranged in length from 34 to 52 years. The observation period for Plant L began in 1949 to avoid methodological problems associated with the earlier fifth revision of the International Classification of Diseases (ICD).[1] These problems include establishing comparability with later revisions and cohort selection factors associated with employment during World War II. Because the four study sites are highly diverse with respect to geographic location, cohort size, cohort entry period, CD exposure period and CD exposure levels [21], we approached all aspects of this investigation in a site-specific manner, combining activities or data across two or more sites only if warranted by evidence of sufficient homogeneity.

Table 2 shows that the CD cohort predominantly comprised white males employed in blue collar (wage earning) positions who terminated employment before the end of the study period. The pay type (blue, white collar) variable was constructed by two of the authors (NE and TH) from detailed work history data for use in our exposure–response analysis for respiratory system cancer as a rough surrogate of education/socioeconomic status [21]. A substantial number of subjects in each plant worked 20 or more years or were followed for mortality 30 or more years. Plants L and M included the largest percentages of short-term workers (less than 5 years). In all plants, the majority of subjects were hired between ages 20 and 29. More than 92% of the workers at each plant were exposed to CD, with 99% of the Louisville workers exposed and all Grenoble workers exposed. Exposure to VC occurred only in Plants L and M with 22.7% and 5.5% of subjects exposed, respectively. By nature of the production process involved, all workers exposed to VC were also exposed to CD.

2.2. *Vital status and cause of death ascertainment*

Study members for U.S. plants with unconfirmed vital status (not known from company-held records to be alive or dead as of the study end date) were entered into the standard UPitt vital status tracing protocol developed by Schall et al. [22,23]. This included a combination of federal and state government sources (e.g., Pension Benefit Information (PBI), the National Death Index (NDI), Social Security Administration (SSA)). A limitation found with this protocol in fall 2004 [24] revealed that relying upon PBI as the first stage of the tracing protocol may not identify all deaths. Due to time limitations, the revised two-stage protocol proposed by Buchanich et al. [24] was not used; instead all cohort members identified

[1] Truncating the Plant L cohort at 1949 resulted in the loss of only three subjects. Two of these had died before 1949 (one from cancer of the intestines (ICD5 = 046e) and one from an automobile accident (ICD5 = 170c)) and one subject was lost to follow-up. Thus, this truncation had negligible effect on our mortality analysis.

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Table 2
Distribution of CD cohort by selected study factors

Characteristic	Louisville, KY		Maydown, NI		Pontchartrain, LA		Grenoble, FR		All plants	
	Number	%	Number	%	Number	%	Number	%	Number	%
Subjects	5507	44.3	4849	39.0	1357	10.9	717	5.8	12,430	100.0
Race										
White	3425	62.1	4849	100.0	698	51.4	717	100	9689	77.9
Non-white	568	10.3	0	0	175	12.9	0	0	743	6.0
Unknown	1514	27.6	0	0	484	35.7	0	0	1998	16.1
Sex										
Male	4895	88.9	4359	89.9	1108	81.6	646	90.1	11,008	88.6
Female	612	11.1	490	10.1	249	18.4	71	9.9	1422	11.4
Worker pay type[a]										
Blue collar	5317	96.6	4503	92.8	947	69.8	518	72.2	11,285	90.8
White collar	190	3.4	346	7.2	410	30.2	199	27.8	1145	9.2
Worker service type										
Short-term (<5 years)	2615	47.5	2713	56.0	426	31.4	150	20.9	5904	47.5
Long-term (5+ years)	2892	52.5	2136	44.1	931	68.6	567	79.1	6526	52.5
Vital status (as of 31 December 2000)										
Alive	3095	56.2	4414	91.0	1255	92.5	630	87.9	9394	75.6
Assumed	(2715)	(87.7)	(4089)	(92.6)	(837)	(66.7)	(374)	(59.4)	(8015)	(85.3)
Confirmed	(380)	(12.3)	(325)	(7.4)	(418)	(33.3)	(256)	(40.6)	(1379)	(14.7)
Dead	2403	43.6	435	9.0	102	7.5	62	8.7	3002	24.2
Cause of death known	(2282)	(95.0)	(412)	(94.7)	(100)	(98.0)	(56)	(90.3)	(2850)	(94.9)
Cause of death unknown	(121)	(5.0)	(23)	(5.3)	(2)	(2.0)	(6)	(9.7)	(152)	(5.1)
Untraceable	9	0.2	0[b]		0		25	3.5	34	0.3
Working status (31 December 2000)										
Active	380	6.9	325	6.7	418	30.8	256	35.7	1379	11.1
Separated	5127	93.1	4501	92.8	912	67.2	461	64.3	11,001	88.5
Died while employed	0	0	23	0.5	27	2.0	0	0	50	0.4
Age at hire										
<20	339	6.2	1172	24.2	112	8.3	36	5.0	1659	13.3
20–29	3280	59.6	2515	51.9	839	61.8	369	51.5	7003	56.3
30+	1888	34.3	1162	24.0	406	29.9	312	43.5	3768	30.3
Duration of employment (years)										
<5	2615	47.5	2713	56.0	426	31.4	150	20.9	5904	47.5
5–19	1100	20.0	1276	26.3	459	33.8	307	42.8	3142	25.3
20+	1792	32.5	860	17.7	472	34.8	260	36.3	3384	27.2
Time since first employment (years)										
<20	497	9.0	1107	22.8	575	42.4	234	32.6	2413	19.4
20–29	1213	22.0	1709	35.2	298	30.0	245	34.2	3465	27.9
30+	3797	69.0	2033	41.9	484	35.7	238	33.2	6552	52.7
CD exposure status										
Unexposed	37	0.7	375	7.7	99	7.3	0	0	511	4.1
Exposed	5470	99.3	4474	92.3	1258	92.7	717	100.0	11,919	95.9
VC exposure status										
Unexposed	4257	77.3	4584	94.5	n/a		n/a		8841	85.4
Exposed	1250	22.7	265	5.5					1515	14.6

[a] Pay type = blue collar if blue collar duration of employment > white collar duration of employment, else pay type = white collar.
[b] An estimated 5% of the NI cohort was lost-to-follow-up and presumed alive for the statistical analysis.

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as presumed alive using the Schall et al. [22,23] methodology were sent to the NDI. This revised methodology ensured that we did not miss deaths for study members who had been presumed alive because NDI has independent agreements with each state to receive all deaths and is not subject to the restrictions identified by Buchanich et al. [24] from relying on information from PBI.

Cause of death acquisition proceeded as described by Schall et al. [22,23]. NDI-Plus was utilized to obtain the coded cause of death for all persons identified as deceased from 1 January 1979 through 31 December 2000. For all study members identified as deceased prior to 1979, a copy of the death certificate was requested from the state health department where the death occurred. We also obtained some coded causes of death for deaths prior to 1979 from the Dupont employee registry. All death certificates were coded to the underlying cause of death by a U.S. National Center for Health Statistics nosologist using the International Classification of Diseases (ICD) rules in effect at the time of death.

Subjects in the Plant M cohort whose vital status was unknown from company-held records were traced for deaths via computerized and manual searches of files available at the General Registry Office (GRO) in Belfast, NI. This activity was performed by GRO staff under the direction of UPitt researchers and a DuPont Chemical Co. consultant based in England. Because GRO did not have access to the mortality registers for the Republic of Ireland, some relatively small percentage of deaths (estimated to be about 5%) that occurred in that area may have been missed. These subjects were assumed alive for purposes of the mortality analysis. For subjects in the Plant G cohort, vital status and cause of death was determined through 1999 (1 year earlier than the remaining sites) by the French investigators who conducted the earlier cancer incidence study of this site [11] and provided the cohort file to UPitt. As for Plant M, a small percentage of deaths in the Plant G cohort may have been missed among subjects who emigrated from France.

Table 2 shows that 3002 deaths were identified among the total CD cohort and underlying cause of death was determined for 2850 or 95%. Cause of death ascertainment rates ranged from 90.3% for Plant G to 98% for Plant P. Lost-to-follow-up rates were 0% for Plant P, 0.2% for Plant L and 3.5% for Plant G.

2.3. Statistical analysis

We examined the total and cause-specific mortality experience of subjects from each CD plant during their respective study period (see Table 1). Cohort analyses were performed using a modified life table procedure from the Occupational Cohort Mortality Program (OCMAP) [25]. Person-years at risk contributed by each subject were jointly classified by race, sex, age group, calendar time, duration of employment (DOE) and the time since first employment (TSFE). Person-year counts began at the beginning of the study period or date of hire (whichever occurred later) and continued until date of death or the end of the study period. For workers lost-to-follow-up, person-year counts stopped at the last date of known vital status, which was employment termination date. Person-years for subjects of unknown race were assigned to white or non-white categories in proportion to the person-year distribution of study members with known race. This same approach was applied separately to assign race to observed deaths of unknown race.

We computed expected numbers of deaths by multiplying average annual race, sex, age and time-specific standard population death rates by the person-years at risk in the corresponding race–sex–age–time intervals. For Plants L and P, expected deaths were computed using as standard populations the total U.S. and the local plant areas (aggregates of counties or parishes) from which the plant workforces were largely drawn (for Plant L: Jefferson and Bullitt KY, Clark, Floyd and Harrison IN; for Plant P: E. Baton Rouge, Jefferson, Ascension, St. Charles, St. James, Tangipahoa and St. John LA). Population-weighted county rates were obtained from the Mortality and Population Data System (MPDS) maintained by UPitt [26]. Due to MPDS data limitations, expected numbers of non-cancer deaths for Plant L were limited to 1960–1994 (with 1962–1964 rates applied to 1960–1964 person-years). Because local death rates usually provide the most valid external mortality comparisons (as they help to adjust for the social, cultural and economic factors related to disease) our analysis of general mortality patterns for the U.S. plants focused primarily on the local county comparisons. Moreover, because the counties or parishes involved represent large population areas, the local rates are measured with good precision. For Plants M and G, we used only the respective national death rates to compute expected deaths.

For each study plant, standardized mortality ratios (SMRs) and their 95% confidence intervals (CI) were computed for all subjects and for selected subgroups. A limited number of SMRs were computed for all study plants combined by forming the ratio of the sum of the plant-specific observed to expected numbers of deaths taken from the plant-specific total study periods. Statistically significant deviations of the SMRs below and above 1.00 were identified using Poisson probabilities [27]. All tests were done at the .05 significance level

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Table 3
Observed (Obs) deaths and SMRs for selected causes of death (total Louisville cohort, U.S. and local county comparisons, 1949–2000[a])

Cause of death (ninth revision ICD codes)	Obs	U.S.		Local county	
		SMR	95% CI	()[b] SMR	95% CI
All causes of death (001–999)	2403	0.82**	0.79–0.86	(2357) 0.74**	0.71–0.77
All cancer (140–208)	652	0.91*	0.84–0.98	0.75**	0.69–0.80
Buccal cavity and pharynx (140–149)	13	0.76	0.41–1.31	0.51**	0.27–0.86
Digestive organs and peritoneum (150–159)	168	0.94	0.80–1.09	0.83*	0.71–0.96
Esophagus (150)	20	0.99	0.60–1.53	0.71	0.44–1.10
Stomach (151)	24	0.92	0.59–1.37	1.10	0.70–1.64
Large intestine (153)	70	1.14	0.89–1.44	0.94	0.73–1.19
Rectum (154)	12	0.87	0.45–1.52	0.80	0.41–1.40
Biliary passages and liver primary (155, 156)	17	1.04	0.60–1.66	0.90	0.52–1.44
Pancreas (157)	22	0.62*	0.39–0.94	0.57**	0.36–0.86
All other digestive (152, 158, 159)	3	0.55	0.11–1.61	0.48	0.10–1.40
Respiratory system (160–165)	266	1.06	0.94–1.19	0.75**	0.66–0.85
Larynx (161)	10	1.13	0.54–2.08	0.75	0.36–1.39
Bronchus, trachea, lung (162)	252	1.05	0.92–1.19	0.75**	0.66–0.85
All other respiratory (160, 163, 164, 165)	4	1.66	0.45–4.25	1.29	0.35–3.30
Breast (174, 175)	10	0.97	0.47–1.79	0.91	0.44–1.67
All uterine (females only) (179, 180, 181, 182)	2	0.71	0.09–2.57	0.61	0.07–2.22
Prostate (males only) (185)	47	0.72*	0.53–0.95	0.68**	0.50–0.91
Kidney (189.0, 189.1, 189.2)	15	0.92	0.52–1.52	0.83	0.46–1.37
Bladder and other urinary organs (188, 189.3, 189.4, 189.8, 189.9)	14	0.77	0.42–1.30	0.69	0.38–1.16
Malignant melanoma of skin (172)	5	0.55	0.18–1.29	0.58	0.19–1.36
Central nervous system (191, 192)	13	0.77	0.41–1.32	0.69	0.37–1.18
Lymphatic–hematopoietic tissue (200–208)	63	0.96	0.74–1.23	0.88	0.68–1.13
Hodgkin's disease (201)	4	0.99	0.27–2.54	0.86	0.23–2.19
Non-Hodgkin's lymphoma (200, 202.0, 202.1, 202.8, 202.9)	23	0.97	0.62–1.46	0.92	0.58–1.37
Leukemia and aleukemia (204–208)	26	1.03	0.68–1.52	0.93	0.60–1.36
All other lymphopoietic tissue (202.2, 202.3, 202.4, 202.5, 202.6, 203)	10	0.79	0.38–1.45	0.74	0.36–1.37
All other malignant neoplasms (171, 173, 195–199)	34	0.62**	0.43–0.87	0.56**	0.39–0.78
Diabetes (250)	47	0.84	0.62–1.12	(47) 0.72*	0.53–0.96
Cerebrovascular disease (430–438)	139	0.79**	0.67–0.94	(138) 0.71**	0.60–0.84
All heart disease (390–398, 402, 404, 410–429)	825	0.77**	0.72–0.83	(817) 0.71**	0.66–0.76
Non-malignant respiratory disease (460–519)	158	0.67**	0.57–0.79	(158) 0.56**	0.47–0.65
Ulcer of stomach and duodenum (531–533)	8	0.68	0.29–1.34	(6) 0.63	0.23–1.38
Cirrhosis of liver (571)	32	0.53**	0.37–0.75	(32) 0.51**	0.35–0.72
Nephritis and nephrosis (580–589)	32	1.11	0.76–1.57	(30) 0.90	0.61–1.29
All external causes of death (E800–999)	130	0.61**	0.51–0.72	(118) 0.63**	0.52–0.75
Accidents (E800–949)	80	0.58**	0.46–0.72	(74) 0.68**	0.53–0.85
Suicides (E950–959)	33	0.72	0.49–1.00	(31) 0.66*	0.45–0.93
Homicides and other external (E960–978, E980–999)	17	0.57*	0.33–0.91	(13) 0.41**	0.22–0.70
Unknown causes	121			(116) 121	

[a] Observation period is 1960–2000 for all causes combined and non-malignant causes of death based on local comparisons.
[b] Observed number of deaths during 1960–2000 study period.
* $p < .05$.
** $p < .01$.

and no adjustment was made for multiple comparisons. The *a priori* statistical power[2] of our study to detect a 2.0-fold or greater excess in lung cancer was 0.87 and 0.97 for Plants G and P, respectively, and essentially 1.00 for Plants L and M and the combined cohort. For liver cancer, the corresponding statistical power was less than 0.25 for Plants G and P, 0.41 for Plant M, 0.97 for Plant L and 0.99 for the combined cohort.

3. Results

Tables 3–6 show for Plants L, P, M and G, respectively, observed deaths and SMRs for the corresponding

[2] The *a priori* statistical power is the probability of obtaining an SMR statistically significantly greater than 1.00 at the 0.05 level (one-sided) assuming no excess risk and estimated numbers of expected deaths.

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Table 4
Observed (Obs) deaths and SMRs for selected causes of death (total Pontchartrain cohort, U.S. and local county comparisons, 1962–2000)

Cause of death (ninth revision ICD codes)	Obs	U.S.		Local county	
		SMR	95% CI	SMR	95% CI
All causes of death (001–999)	102	0.57**	0.46–0.69	0.53**	0.43–0.65
All cancer (140–208)	34	0.74	0.51–1.04	0.68*	0.47–0.95
Digestive organs and peritoneum (150–159)	7	0.66	0.26–1.35	0.63	0.25–1.29
Large intestine (153)	3	0.84	0.17–2.46	0.78	0.16–2.27
Rectum (154)	2	2.62	0.32–9.47	3.06	0.37–11.04
Biliary passages and liver primary (155, 156)	0	–	0–3.11	–	0–2.39
Respiratory system (160–165)	12	0.72	0.37–1.26	0.62	0.32–1.09
Larynx (161)	1	1.81	0.05–10.11	1.46	0.04–8.12
Bronchus, trachea, lung (162)	10	0.63	0.30–1.16	0.55	0.26–1.00
All other respiratory (160, 163, 164, 165)	1	6.00	0.15–33.42	4.25	0.11–23.68
Malignant melanoma of skin (172)	2	1.97	0.24–7.10	2.03	0.25–7.34
Central nervous system (191, 192)	3	1.88	0.39–5.50	1.95	0.40–5.70
Lymphatic–hematopoietic tissue (200–208)	5	1.05	0.34–2.45	1.03	0.33–2.40
Non-Hodgkin's lymphoma (200, 202.0, 202.1, 202.8, 202.9)	2	1.05	0.13–3.78	0.99	0.12–3.57
Leukemia and aleukemia (204–208)	2	1.13	0.14–4.07	1.11	0.13–4.01
All other malignant neoplasms (171, 173, 195–199)	2	0.52	0.06–1.89	0.44	0.05–1.58
Cerebrovascular disease (430–438)	2	0.30	0.04–1.06	0.28	0.03–1.01
All heart disease (390–398, 402, 404, 410–429)	26	0.49**	0.32–0.72	0.44**	0.29–0.64
Non-malignant respiratory disease (460–519)	3	0.28*	0.06–0.80	0.33*	0.07–0.96
All external causes of death (E800–999)	18	0.65	0.38–1.02	0.59*	0.35–0.93
Accidents (E800–949)	14	0.89	0.48–1.49	0.82	0.45–1.37
Suicides (E950–959)	2	0.31	0.04–1.12	0.28	0.03–1.01
Homicides and other external (E960–978, E980–999)	2	0.36	0.04–1.30	0.31	0.04–1.12
Unknown causes (in all causes category only)	2				

* $p < .05$.
** $p < .01$.

total study period. Shown in each table are all cause of death categories from our MPDS listing [26] that included at least two observed deaths (or at least one death for liver cancer). For Plant L (Table 3), the local county comparisons revealed statistically significant deficits in deaths for all causes of death combined (SMR = 0.74, 95% CI = 0.71–0.77) and all cancers combined (SMR = 0.75, 95% CI = 0.69–0.80). Deficits in deaths were also observed for nearly all the malignant and non-malignant cause of death categories examined, and many were statistically significant. We observed a statistically significant 25% deficit in respiratory system cancer (RSC) based on 266 deaths (SMR = 0.75, 95% CI = 0.66–0.85). Of these, 252 or 95% were due to cancer of the bronchus, trachea or lung, which yielded a similar deficit (SMR = 0.75, 95% CI = 0.66–0.85). For the other cancer site of *a priori* interest in this study, liver cancer (categorized as cancer of the biliary passages and liver), we observed a 10% local county rate-based deficit in mortality based on 17 deaths (SMR = 0.90, 95% CI = 0.52–1.44). Based on their ICD codes, the 17 liver cancer deaths included seven "liver primary" (ICD9 = 155.0), four "extrahepatic bile ducts" (ICD9 = 156.1), three "gall bladder" (ICD9 = 156.0), one "intrahepatic bile ducts" (ICD9 = 155.1), one "liver cell carcinoma" (ICD10 = C22.0), and one "biliary tract, unspecified" (ICD10 = C24.9). With only a few exceptions, the corresponding SMRs based on U.S. rates are higher, reflecting the generally higher total and cause-specific rates of the Louisville, KY regional area. This disparity for many of the chronic disease categories is at least partly due to the higher prevalence of cigarette smoking associated with the state of Kentucky and presumably the Louisville regional area. In fact, Kentucky had the highest prevalence of cigarette smoking of any state in 1997 [28,29].

For Plant P (Table 4), the local county comparisons revealed a statistically significant 47% deficit in deaths for all causes of death combined (SMR = 0.53, 95% CI = 0.43–0.65) and a statistically significant 32% deficit for all cancers combined (SMR = 0.68, 95% CI = 0.47–0.95). We observed elevated SMRs for several of the cancer site categories examined, however, most were based on small numbers of observed deaths and none was statistically significant. SMRs for all non-malignant cause of death categories exam-

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Table 5
Observed (Obs) deaths and SMRs for selected causes of death (total Maydown study cohort, Northern Ireland comparison, 1960–2000)

Cause of death (ninth revision ICD codes)	Obs	SMR	95% CI
All causes of death (001–999)	435	0.60**	0.55–0.67
All cancer (140–208)	128	0.68**	0.56–0.80
Digestive organs and peritoneum (150–159)	39	0.65**	0.46–0.89
Esophagus (150)	2	0.23*	0.03–0.84
Stomach (151)	17	1.23	0.72–1.98
Large intestine (153)	7	0.45*	0.18–0.93
Rectum (154)	7	1.07	0.43–2.21
Biliary passages and liver (155, 156)	1	0.24	0.01–1.34
Pancreas (157)	4	0.49	0.13–1.26
Respiratory system (160–165)	48	0.79	0.58–1.05
Bronchus, trachea, lung (162)	43	0.78	0.56–1.05
Prostate (males only) (185)	8	0.84	0.36–1.65
Central nervous system (191, 192)	6	0.84	0.31–1.82
Bone (170)	2	2.69	0.33–9.73
Lymphatic–hematopoietic tissue (200–208)	15	0.90	0.51–1.49
Hodgkin's disease (201)	2	0.31	0.04–1.12
Leukemia and aleukemia (204–208)	3	0.55	0.11–1.62
Benign neoplasms (210–229)	3	0.75	0.16–2.20
Diabetes mellitus (250)	2	0.60	0.07–2.18
Cerebrovascular disease (430–438)	31	0.69*	0.47–0.98
All heart disease (390–398, 402, 404, 410–429)	151	0.60**	0.51–0.70
Non-malignant respiratory disease (460–519)	22	0.34**	0.21–0.51
Cirrhosis of liver (571)	4	0.55	0.15–1.42
Nephritis and nephrosis (580–589)	5	1.16	0.38–2.70
All external causes of death (E800–999)	32	0.38**	0.26–0.54
Accidents (E800–949)	32	0.61**	0.42–0.86
Unknown causes (in all causes category only)	23		

* $p < .05$.
** $p < .01$.

ined were less than 1.00 and some deficits were statistically significant. We observed a 38% deficit in respiratory system cancer (RSC) based on 12 deaths (SMR = 0.62, 95% CI = 0.32–1.09). Of these, 10 or 83% were due to cancer of the bronchus, trachea or lung, which yielded an even larger deficit (SMR = 0.55, 95% CI = 0.26–1.00). No deaths from liver cancer were observed at Plant P. SMRs based on U.S. rates were gen-

Table 6
Observed (Obs) deaths and SMRs for selected causes of death (total Maydown study cohort, Northern Ireland comparison, 1966–1999)

Cause of death (ninth revision ICD codes)	Obs	SMR	95% CI
All causes of death (001–999)	62	0.65**	0.50–0.83
All cancer (140–208)	20	0.59*	0.36–0.91
Buccal cavity and pharynx (140–149)	2	0.65	0.08–2.34
Digestive organs and peritoneum (150–159)	4	0.43	0.12–1.09
Large intestine (153)	2	1.19	0.14–4.28
Biliary passages and liver primary (155, 156)	1	0.56	0.01–3.12
Respiratory system (160–165)	10	0.85	0.41–1.56
Larynx (161)	3	1.88	0.39–5.49
Bronchus, trachea, lung (162)	4	0.47	0.13–1.20
All other respiratory (160, 163, 164, 165)	3	2.55	0.53–7.46
All heart disease (390–398, 402, 404, 410–429)	14	1.06	0.58–1.78
All external causes of death (E800–999)	12	0.72	0.37–1.25
Unknown causes (in all causes category only)	6		

* $p < .05$.
** $p < .01$.

Please cite this article as: Gary M. Marsh et al., Mortality patterns among industrial workers exposed to chloroprene and other substances, Chemico-Biological Interactions (2006), doi:10.1016/j.cbi.2006.08.011

Table 7
Observed (Obs) deaths and SMRs for all cancers combined by selected study factors and plant, local county comparisons (KY and LA), national comparisons (NI and FR)

Study factor	Louisville, KY (1949–2000)		Maydown, NI (1960–2000)		Pontchartrain, LA (1962–2000)		Grenoble, FR (1966–1999)		All plants	
	Obs	SMR (95% CI)	Obs	SMR (95% CI)	Obs	SMR (95% CI)	Obs	SMR (95% CI)	Obs	SMR (95% CI)
All workers	652	0.75** (0.69–0.80)	128	0.68** (0.56–0.80)	34	0.68* (0.47–0.95)	20	0.59* (0.36–0.91)	834	0.73** (0.68–0.78)
Race										
White	561	0.77** (0.71–0.84)	128	0.68** (0.56–0.80)	30	0.66* (0.44–0.94)	20	0.59* (0.36–0.91)	739	0.74** (0.69–0.80)
Non-white	91	0.62** (0.50–0.75)	–	–	4	0.91 (0.25–2.32)	–	–	95	0.62** (0.51–0.76)
Sex										
Male	616	0.75** (0.69–0.81)	126	0.71** (0.59–0.85)	32	0.69* (0.47–0.97)	19	0.59* (0.35–0.92)	793	0.74** (0.69–0.79)
Female	36	0.67* (0.47–0.93)	2	0.16** (0.02–0.59)	2	0.60 (0.07–2.17)	1	0.70 (0.02–3.92)	41	0.58** (0.41–0.78)
Worker pay type										
Blue collar	636	0.75** (0.69–0.81)	123	0.70** (0.49–0.95)	20	0.59* (0.36–0.91)	16	0.67 (0.38–1.09)	795	0.74** (0.68–0.79)
White collar	16	0.67 (0.38–1.09)	5	0.28** (0.09–0.66)	14	0.84 (0.46–1.42)	4	0.40 (0.11–1.03)	39	0.57** (0.41–0.78)
Worker service type										
Short-term (<5 years)	281	0.74** (0.66–0.83)	39	0.47** (0.34–0.65)	3	0.53 (0.11–1.55)	5	0.89 (0.29–2.07)	328	0.69** (0.62–0.77)
Long-term (5+ years)	371	0.75** (0.67–0.83)	89	0.80* (0.64–0.98)	31	0.70* (0.48–0.99)	15	0.53* (0.30–0.88)	506	0.75** (0.68–0.81)
Duration of employment										
<5	281	0.73** (0.65–0.82)	39	0.45** (0.32–0.62)	3	0.42 (0.09–1.23)	5	0.71 (0.23–1.65)	328	0.68** (0.60–0.75)
5–19	107	0.63** (0.51–0.76)	51	0.72* (0.53–0.94)	22	0.86 (0.54–1.31)	9	0.46* (0.21–0.88)	189	0.66** (0.57–0.76)
20+	264	0.82** (0.72–0.93)	38	1.02 (0.72–1.40)	9	0.44** (0.20–0.84)	6	0.83 (0.31–1.82)	317	0.82* (0.73–0.91)
Time since first employment										
<20	51	0.52** (0.39–0.68)	30	0.53** (0.36–0.76)	16	0.93 (0.53–1.51)	9	0.61** (0.42–0.86)	106	0.57** (0.47–0.69)
20–29	118	0.72** (0.59–0.86)	58	0.77* (0.58–0.99)	11	0.56 (0.28–1.01)	8	0.57 (0.24–1.12)	195	0.71** (0.62–0.82)
30+	483	0.79** (0.72–0.86)	40	0.64** (0.45–0.87)	7	0.53 (0.21–1.09)	3	0.83 (0.17–2.43)	533	0.77** (0.71–0.84)
CD exposure status										
Unexposed	1	0.99 (0.03–5.51)	14	1.26 (0.69–2.12)	8	1.44 (0.62–2.85)	5	0.61 (0.20–1.42)	28	1.08 (0.72–1.56)
Exposed	651	0.74** (0.69–0.80)	114	0.62** (0.51–0.75)	26	0.57** (0.37–0.84)	15	0.59* (0.33–0.97)	806	0.71** (0.66–0.76)
VC exposure status										
Unexposed	524	0.80** (0.73–0.87)	113	0.64** (0.53–0.77)	34	0.68* (0.47–0.95)	20	0.59 (0.36–0.91)	691	0.75** (0.70–0.81)
Exposed	128	0.58** (0.49–0.69)	15	0.80 (0.44–1.31)	–	–	–	–	143	0.60* (0.50–0.70)

* $p < .05$.
** $p < .01$.

Table 8
Observed (Obs) deaths and SMRs for respiratory system cancer by selected study factors and plant, local county comparisons (KY and LA), national comparisons (NI and FR)

Study factor	Louisville, KY (1949–2000)		Maydown, NI (1960–2000)		Pontchartrain, LA (1962–2000)		Grenoble, FR (1966–1999)		All plants	
	Obs	SMR (95% CI)	Obs	SMR (95% CI)	Obs	SMR (95% CI)	Obs	SMR (95% CI)	Obs	SMR (95% CI)
All workers	266	0.75** (0.66–0.85)	48	0.79 (0.58–1.05)	12	0.62 (0.32–1.09)	10	0.85 (0.41–1.56)	336	0.75** (0.67–0.84)
Race										
White	233	0.78** (0.69–0.89)	48	0.79 (0.58–1.05)	10	0.55* (0.23–0.96)	10	0.85 (0.41–1.56)	301	0.77** (0.69–0.87)
Non-white	33	0.59** (0.40–0.83)	–	–	2	1.56 (0.17–4.91)	–	–	35	0.61** (0.42–0.85)
Sex										
Male	256	0.75** (0.66–0.85)	48	0.82 (0.60–1.08)	11	0.59 (0.30–1.06)	10	0.86 (0.41–1.58)	325	0.76** (0.68–0.84)
Female	10	0.72 (0.34–1.31)	0	– (0–2.01)	1	1.38 (0.04–7.71)	0	– (0–30.70)	11	0.66 (0.33–1.18)
Worker pay type										
Blue collar	262	0.76** (0.67–0.86)	46	0.81 (0.60–1.08)	8	0.62 (0.27–1.21)	9	1.09 (0.50–2.06)	325	0.77** (0.69–0.86)
White collar	4	0.41 (0.11–1.04)	2	0.36 (0.04–1.29)	4	0.63 (0.17–1.61)	1	0.29 (0.01–1.59)	11	0.44** (0.22–0.78)
Worker service type										
Short-term (<5 years)	123	0.80* (0.66–0.95)	14	0.57* (0.30–0.93)	0	– (0–2.08)	2	1.04 (0.13–3.77)	139	0.76* (0.64–0.90)
Long-term (5+ years)	143	0.72** (0.60–0.84)	34	0.92 (0.64–1.28)	12	0.69 (0.36–1.20)	8	0.81 (0.35–1.60)	197	0.75** (0.65–0.86)
Duration of employment (years)										
<5	123	0.79** (0.66–0.95)	14	0.54* (0.29–0.90)	0	– (0–1.70)	2	0.86 (0.10–3.12)	139	0.75** (0.63–0.88)
5–19	37	0.58** (0.41–0.79)	24	1.03 (0.66–1.53)	8	0.81 (0.35–1.59)	6	0.90 (0.33–1.96)	75	0.72* (0.57–0.91)
20+	106	0.79** (0.64–0.95)	10	0.78 (0.37–1.43)	4	0.48 (0.13–1.22)	2	0.71 (0.09–2.58)	122	0.77* (0.64–0.92)
Time since first employment (years)										
<20	15	0.46** (0.26–0.76)	14	0.83 (0.45–1.39)	4	0.68 (0.18–1.73)	4	0.74 (0.20–1.89)	37	0.61** (0.43–0.84)
20–29	50	0.72* (0.53–0.95)	19	0.77 (0.46–1.20)	5	0.63 (0.20–1.47)	6	1.17 (0.43–2.55)	80	0.75* (0.59–0.93)
30+	201	0.80** (0.69–0.92)	15	0.73 (0.41–1.21)	3	0.56 (0.12–1.65)	0	– (0–2.95)	219	0.79* (0.69–0.90)
CD exposure status										
Unexposed	0	– (0–8.99)	4	1.15 (0.31–2.93)	0	– (0–1.88)	2	0.79 (0.10–2.84)	6	0.71 (0.26–1.55)
Exposed	266	0.75** (0.66–0.85)	44	0.75 (0.54–1.01)	12	0.68 (0.35–1.18)	8	0.87 (0.37–1.70)	330	0.75** (0.67–0.84)
VC exposure status										
Unexposed	232	0.89 (0.78–1.02)	43	0.77 (0.56–1.04)	12	0.62 (0.32–1.09)	10	0.85 (0.41–1.56)	297	0.85* (0.76–0.96)
Exposed	34	0.36** (0.25–0.50)	5	0.78 (0.25–1.82)	–	–	–	–	39	0.39** (0.27–0.53)

* $p < .05$.
** $p < .01$.

erally somewhat higher than those based on the local parishes.

For Plant M (Table 5), the Northern Ireland national comparisons revealed statistically significant deficits in deaths for all causes of death combined (SMR = 0.60, 95% CI = 0.55–0.67) and all cancers combined (SMR = 0.68, 95% CI = 0.56–0.80). Deficits in deaths were also observed for nearly all the malignant and non-malignant cause of death categories examined, and many were statistically significant. We observed a not statistically significant 21% deficit in respiratory system cancer (RSC) based on 48 deaths (SMR = 0.79, 95% CI = 0.58–1.05). Of these, 43 or 90% were due to cancer of the bronchus, trachea or lung, which yielded a similar deficit (SMR = 0.78, 95% CI = 0.56–1.05). One death from liver cancer was observed in Plant M (SMR not calculated) and was coded as "liver cancer-unspecified" (ICD10 = C22.9).

For Plant G (Table 6), the French national comparisons revealed statistically significant deficits in deaths for all causes of death combined (SMR = 0.65, 95% CI = 0.50–0.83) and all cancers combined (SMR = 0.59, 95% CI = 0.36–0.91). We observed elevated SMRs for some of the cancer sites and non-malignant disease categories examined, however, most were based on small numbers of observed deaths and none was statistically significant. We observed a 15% deficit in respiratory system cancer (RSC) based on 10 deaths (SMR = 0.85, 95% CI = 0.41–1.56). Of these, only 4 or 40% were due to cancer of the bronchus, trachea or lung, which yielded a much larger deficit (SMR = 0.47, 95% CI = 0.13–1.20). One death from liver cancer was observed in Plant G (SMR = 0.56, 95% CI = 0.01–3.12), and was coded as "liver, not specified as primary or secondary" (ICD9 = 155.2).

Table 9
Observed (Obs) deaths and SMRs for liver cancer by selected study factors, Louisville Plant, local county comparisons

Study factor	Louisville, KY (1949–2000)		All plants combined[a]	
	Obs	SMR (95% CI)	Obs	SMR (95% CI)
All workers	17	0.90 (0.53–1.44)	19	0.72 (0.43–1.13)
Race				
White	16	1.02 (0.58–1.65)	18	0.78 (0.46–1.23)
Non-white	1	0.32 (0.01–1.77)	1	0.30 (0.004–1.67)
Sex				
Male	16	0.89 (0.51–1.45)	18	0.72 (0.43–1.13)
Female	1	1.06 (0.03–5.93)	1	0.87 (0.01–4.87)
Worker pay type				
Blue collar	17	0.93 (0.54–1.49)	18	0.73 (0.43–1.16)
White collar	0	– (0–6.91)	1	0.66 (0.009–3.67)
Worker service type				
Short-term (<5 years)	4	0.49 (0.13–1.26)	4	1.54 (0.41–3.94)
Long-term (5+ years)	13	1.21 (0.64–2.07)	15	0.88 (0.49–1.45)
Duration of employment (years)				
<5	4	0.49 (0.13–1.25)	4	0.41 (0.11–1.06)
5–19	6	1.68 (0.62–3.66)	7	1.02 (0.41–2.09)
20+	7	0.98 (0.40–2.03)	8	0.97 (0.42–1.91)
Time since first employment (years)				
<20	1	0.56 (0.01–3.11)	1	0.29 (0.004–1.60)
20–29	3	0.91 (0.19–2.66)	4	0.71 (0.19–1.81)
30+	13	0.95 (0.50–1.62)	14	0.88 (0.48–1.47)
CD exposure status				
Unexposed	0	– (0–134.59)	2	2.56 (0.29–9.25)
Exposed	17	0.90 (0.53–1.44)	17	0.71 (0.42–1.14)
VC exposure status				
Unexposed	15	1.07 (0.60–1.77)	17	0.80 (0.47–1.29)
Exposed	2	0.44 (0.05–1.49)	2	0.40 (0.05–1.46)

[a] Includes observed and expected deaths from all four study plants.

Please cite this article as: Gary M. Marsh et al., Mortality patterns among industrial workers exposed to chloroprene and other substances, Chemico-Biological Interactions (2006), doi:10.1016/j.cbi.2006.08.011

Tables 7–9 show for all cancers combined, RSC and liver cancer, respectively, observed deaths and SMRs by selected study factors and plant, including the four plants combined. SMRs for Plants L and P are based on local county rates; those for Plants M and G on the respective national rates. For all cancers combined (Table 7), the aggregate SMR reflects a statistically significant 27% deficit in deaths based on 834 observed deaths (SMR = 0.73, 95% CI = 0.68–0.78) for the total CD cohort. For nearly all of the study variables and subcategories examined, including the variables that are surrogates of occupational exposure to CD or other substances (i.e., worker pay type, worker service type, duration of employment and the time since first employment), we observed deficits in deaths within and across the four plants and many are statistically significant. None of the few elevated SMRs in Table 7 was statistically significant. Because most of the cohort was exposed to CD, most of the cancer deaths occurred among CD-exposed persons (806/834), resulting in a statistically significant 29% deficit in all cancer mortality. Although plant-specific SMRs for CD-unexposed subjects are relatively imprecise due to the much smaller numbers of observed deaths, all cancer SMRs are higher within and across plants for CD-unexposed subjects compared with subjects who had some CD exposure. For Plants L and M where potential VC exposure occurred, we observed a combined statistically significant 40% deficit in all cancer deaths (SMR = 0.60, 95% CI = 0.50–0.70) based on 143 deaths. SMRs for workers both exposed and unexposed to VC were less than 1.00 in each plant.

For RSC (Table 8), the aggregate SMR reflects a statistically significant 25% deficit in deaths based on 336 observed deaths (SMR = 0.75, 95% CI = 0.67–0.84) for the total CD cohort. For nearly all of the study variables and subcategories examined, including the CD exposure variable and the variables that act as surrogates of exposure to CD or other substances, we observed deficits in deaths within and across the four plants and many are statistically significant. None of the few elevated SMRs in Table 8 was statistically significant. With the exception of a slight RSC excess among workers unexposed to CD in Plant M, SMRs for workers unexposed and exposed to CD or VC were less than 1.00.

Because 17 of the 19 total liver cancer deaths occurred in Plant L, the subgroup analysis was limited to Plant L and the combined four plants (Table 9). Based on the 19 deaths, we observed a 28% deficit in liver cancer deaths for the total CD cohort. All but one death occurred among white male, blue collar subjects. All of the 17 liver cancer deaths in Plant L occurred among subjects who had been exposed to CD, resulting in 10% deficit in deaths (SMR = 0.90, 95% CI = 0.53–1.44). For the combined plants, elevated SMRs were observed among short-term workers, workers employed 5–19 years, and among workers unexposed to CD; however, none was statistically significant.

4. Discussion and conclusions

Our historical cohort study of workers from four CD production sites in the U.S. and Europe represents the largest and the most comprehensive and rigorous investigation of the long-term health effects of exposure to CD conducted to date. It overcomes most of the shortcomings and uncertainties noted by Rice and Boffetta [30] and Acquavella and Leonard [31] that have limited the interpretation of findings from the five previous cohort studies, that is, the studies of chloroprene production workers in the U.S. [6], China [7], Armenia [8] and France [11] and the study of shoe manufacturing workers in Russia [9].

Our combined cohort of 12,430 subjects contributed over one-third of a million person-years of observation, of which 151,691 or 41% were among workers followed for 20 or more years from first employment. Through 2000 (1999 for Plant G), we observed 3002 deaths, including 834 from all cancers combined. For the two cause of death categories of *a priori* interest in this study (respiratory system cancer and liver cancer (categorized as cancer of the biliary passages and liver)), we observed 336 and 19 deaths, respectively. Other major strengths of the study include: diversity of site location and production processes; long observation periods; substantial proportion of workers employed 20 or more years; nearly complete cohort enumeration with cross-validation, vital status tracing and cause of death determination; excellent statistical power to detect two-fold or greater overall mortality excess for all cause of death categories of *a priori* interest; a rigorous and innovative, chemical process-based exposure reconstruction for chloroprene and vinyl chloride; and the use of national and local county mortality comparisons and robust statistical modeling of internal cohort rates.

During the course of the study, we attempted to locate, from records held by the two U.S. plants and Plant M, tobacco-smoking histories for all subjects who died from RSC and a series of control subjects to permit adjustment for potential confounding by smoking via a nested case-control study. Because we found that only 28% of the RSC cases from Plant L and 54% from Plant M had smoking history information, we decided that the case-control study of RSC was unfeasible. Two features of our cohort study, however, enabled at least

Please cite this article as: Gary M. Marsh et al., Mortality patterns among industrial workers exposed to chloroprene and other substances, Chemico-Biological Interactions (2006), doi:10.1016/j.cbi.2006.08.011

some crude adjustment for potential confounding by smoking. First, in the two U.S. plants, our use of local county mortality comparisons afforded some adjustment for geographic variability in tobacco use. This was particularly evident in Plant L where SMRs for RSC and most other smoking-related chronic diseases based on local rates were considerably less than those based on U.S. rates. Second, in the exposure–response analyses for CD and VC described in our companion paper [21], we categorized workers by pay type (blue/white collar) and used this variable as a rough surrogate of education and socioeconomic status, which are highly correlated with smoking prevalence in both the U.S. and Europe.

While the *a priori* statistical power of our study to detect an overall two-fold or greater excess in liver cancer was 99%, the power was much lower in all plants but Plant L (which included 17 of the total 19 liver cancer deaths) and in other cohort subgroups examined. However, the issue of statistical power for liver cancer in this study was rendered mostly moot, as most of the SMRs were less than the null hypothesis value of 1.00 that was tested with a one-tailed test (i.e., with a one-tailed statistical test of the null hypothesis SMR = 1.00 versus the alternative hypothesis SMR > 1.00, power only applies to values observed under the alternative hypothesis).

In addition to CD and to VC in Plants L and M, subjects in our study plants were also potentially exposed to other agents, including 1,3-butadiene, 1,4-dichloro-2-butene, 3,4-dichloro-1-butene and methylene chloride. However, because exposures to these agents were brief, intermittent and process-specific, they would have had negligible or no impact on long-term worker health effects, thus, we made no attempt to characterize these or other co-exposures.

About one-half of the CD cohort were short-term workers (defined as working less than 5 years) although 27% of subjects worked 20 or more years. Contrary to many other occupational cohort studies, short-term workers did not exhibit a differential mortality pattern often associated with increased mortality for both malignant and non-malignant diseases. The long length of follow-up in this study may have mitigated the mortality influence of short-term workers. Potential selection bias from the subjects lost to follow-up in Plant M or the transferred workers missed in Plant P, or underestimation of cause-specific SMRs in Plant G may be operating in our study, but the overall effects would be minimal due to the small percentage of subjects involved. Because we did not adjust *p*-values for multiple comparisons, some of our statistically significant SMRs may be simply chance occurrences.

The total and cause-specific mortality patterns observed in this study were generally quite consistent across plants and indicated a statistically significant reduced mortality risk from all causes combined, all cancer sites combined and from many of the other malignant and non-malignant disease categories examined. Moreover, these reduced risks were maintained in all cohort subgroups examined, including the CD and VC exposure variables (never/ever exposed to CD or VC), and the variables that serve as surrogates of exposure to CD or other substances found in the study plants (worker pay type (blue/white collar), worker service type (short/long term), duration of employment and the time since first employment). These favorable mortality patterns, particularly those for the long-term chronic diseases examined, are probably influenced in part by the "healthy worker effect", a relative absence of deleterious health risks in relation to employment, and the effects of continuing employment with its many benefits, such as improved health care and quality of life.

Of particular importance is our finding of no elevated mortality risks for all cancers combined or for the two *a priori* cancer sites of interest, lung (evaluated separately and within the slightly broader respiratory system cancer category) and liver (categorized as cancer of the biliary passages and liver). Our finding of no excess risk for liver cancer is reassuring, considering that during the course of this investigation, we learned that the acetylene manufacturing process for chloroprene used in Plants L and M produced vinyl chloride exposures as a by-product [17–20]. VC is an established risk factor for a rare form of liver cancer (angiosarcoma) and is also linked to other forms of cancer including hepatocellular carcinoma, brain tumors, lung tumors and malignancies of the lymphatic and hematopoietic system [32]. Excess liver cancers were also reported in experimental studies of animals exposed to CD [16] and in three previous epidemiology studies of workers with potential exposure to CD: workers in a chloroprene monomer production facility in China [7], shoe manufacturing workers in Moscow [9] and chloroprene production workers in Armenia [8]. The inherent methodological limitations in the previous epidemiology studies raise questions, however, about their significance regarding human cancer risks [30,31].

In our study, we examined liver cancer within the broader cause of death category "biliary passages and liver" and found no evidence of an increased risk of death in the total cohort (Plant L included 17 of 19 deaths) or within any of the cohort subgroups examined. Of the 19 deaths coded to this broader liver cancer category, only eight were coded as a primary liver cancer. We found no evidence of increased mortality risks for the other

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cancer sites linked to VC exposure. As noted in our companion papers, the absence of any elevated cancer risks among VC-exposed subjects in our study is most likely explained by the relatively low historical VC exposures in Plants L and M [17–21].

While the possible occurrence of the rare VC-related cancer, angiosarcoma of the liver, was of interest in this study, methodological limitations precluded a full evaluation. Because angiosarcoma of the liver does not have a specific ICD code until the 10th revision (1999+), it can only be roughly identified in earlier revisions by manually reviewing text fields of death certificates. A comprehensive death certificate review was not possible in this study as we obtained death certificates for the two U.S. plants only for deaths that occurred before the National Death Index (before 1979) and in some cases cause of death for pre-1979 deaths was obtained as an ICD code from the DuPont mortality registry. For Plant G we obtained ICD codes only from our French collaborators and in Plant M we obtained only a limited number of death certificates. What we were able to glean from available data follows.

Seventeen of the 19 deaths coded to cancer of "biliary passages and liver" occurred in Plant L. Only four of these occurred before 1979 and death information was obtained for three from the DuPont mortality registry as an ICD code only. Thus, of the 17 Plant L deaths, we had a copy of the death certificate for only one death. The cause of death on this certificate was noted as "liver cancer". Two of the 17 Plant L deaths occurred during the time-period of the ICD10 (1999 and 2000). One was coded as C249 "malignant neoplasms of digestive organs – malignant neoplasm of other and unspecified parts of biliary tract – biliary tract, unspecified" and one was coded as C220 "malignant neoplasms of digestive organs – malignant neoplasm of liver and intrahepatic bile ducts – liver cell carcinoma". The one Plant M liver cancer death was coded to ICD10 as C229 "malignant neoplasm of liver and intrahepatic bile ducts—liver, unspecified". The exact wording on that death certificate was "cancer of the liver". The possible occurrence of angiosarcoma of the liver would be best evaluated in a cancer incidence study that would utilize more detailed histo-pathological and other information not available on death certificates.

Our finding of no excess risk for respiratory system cancer (of which more than 90% were cancers of the bronchus, trachea or lung, i.e., lung cancer) is also reassuring considering the suggestion of a lung cancer excess in the cohort incidence study of chloroprene production workers in France [11] that formed the basis of our mortality study in Plant G. For several reasons, the results of our cohort mortality study for Plant G are not directly comparable with the previously published cancer incidence study. While both studies included the same facility, the cancer incidence study was limited by entrance criteria not used in the mortality study. Specifically, the cancer incidence study did not include women, employees who worked less than 2 years or subjects who left the Isère region of France before 1979. Also, the cancer incidence and vital status tracing done for the two studies used independent French government data sources. The cancer incidence study used the cancer registry of the Department of Isère for the identification of cancer cases. This regional cancer registry covers the area surrounding the plant and includes cancer diagnosis information for approximately one million inhabitants. The cohort mortality tracing used the nationwide INSERM death registry; this agency records the death information for all residents of France. Because the two agencies cover different populations and record different events, the results of tracing the same study cohort through each service cannot be directly compared. Our finding of no excess lung cancer risk among CD-exposed workers was not entirely unexpected, considering what is now known from experimental animal studies about substantial interspecies differences in sensitivity to CD-induced lung tumorigenicity and how these findings can be extrapolated to estimate human lung cancer risk [14,33,34].

In summary, our study has many strengths and is the most definitive study of the human carcinogenic potential of exposure to CD conducted to date. We conclude from this analysis of general mortality patterns that persons exposed to chloroprene at the levels encountered in the four study sites did not have elevated risks of mortality from any of the causes of death examined, including all cancers combined and lung and liver cancer, the cancer sites of *a priori* interest. This conclusion is corroborated by our detailed analyses of mortality in relation to qualitative and quantitative exposures to CD and VC at each of the four study sites, reported in our companion paper [21].

Acknowledgments

The International Institute of Synthetic Rubber Producers (IISRP) sponsored this research, but the design, conduct, analysis and conclusions are those of the authors. Sponsoring companies were DuPont Dow Elastomers LLC and Enichem Elastomers France. We would like to acknowledge the cooperation and support of the representatives and consultants of IISRP and its member companies, in particular, Sheila Jones, Robin Leonard, Mike Lynch, Stuart Pollard and Paul Poullet. Our special thanks to Dr. Marc Colonna of the Registre du Can-

Please cite this article as: Gary M. Marsh et al., Mortality patterns among industrial workers exposed to chloroprene and other substances, Chemico-Biological Interactions (2006), doi:10.1016/j.cbi.2006.08.011

cer de l'Isère who coordinated the cohort enumeration and vital status tracing of the Grenoble, France cohort and provided us with a copy of the data file. In addition, we acknowledge the computer programming work of Stephen Sefcik. The research proposal was approved by the Institutional Review Boards (IRB) of the University of Pittsburgh, the University of Oklahoma and the University of Illinois at Chicago. Portions of the data were presented at the 2005 annual meeting of the British Occupational Hygiene Society, April 19, 2005, Manchester, U.K. and the 2005 annual meeting of the American Industrial Hygiene Association, May 25, 2005, Anaheim, CA.

References

[1] J. Lynch, BD monomer and elastomer production processes, Chem. Biol. Interact. 135–136 (2001) 147–153.
[2] R. Waxweiler, W. Stringer, J. Wagoner, J. Jones, H. Falk, C. Carter, Neoplastic risk among workers exposed to vinyl chloride, Ann. N.Y. Acad. Sci. 271 (1976) 40–48.
[3] P. Infante, Carcinogenic and mutagenic risks associated with some halogenated olefins, Environ. Health Perspect. 21 (1977) 251–254.
[4] E. Khachatryan, The occurrence of lung cancer among people working with chloroprene, Vop. Onkol. 18 (1972) 85–86.
[5] E. Khachatryan, The role of chloroprene compounds in the process of skin neoplasm formation, Gig. Tr. Prof. Zabol. 16 (1972) 54–55.
[6] S. Pell, Mortality of workers exposed to chloroprene, J. Occup. Med. 20 (1978) 21–29.
[7] L. Shouqi, D. Quinan, L. Yuqing, L. Yingfei, Epidemiologic study of cancer mortality among chloroprene workers, Biomed. Environ. Sci. 2 (1989) 141–149.
[8] M. Bulbulyan, A. Margaryan, S. Ilychova, S. Astashevsky, S. Uloyan, V. Cogan, D. Colin, P. Boffetta, D. Zaridze, Cancer incidence and mortality in a cohort of chloroprene workers from Armenia, Int. J. Cancer 81 (1999) 31–33.
[9] M. Bulbulyan, O. Changuina, D. Zaridze, S. Astashevsky, D. Colin, P. Boffetta, Cancer mortality among Moscow shoe workers exposed to chloroprene, Cancer Causes Control 9 (4) (1998) 381–387.
[10] D. Zaridze, M. Bulbulyan, O. Changuina, A. Margaryan, P. Boffetta, Cohort studies of chloroprene-exposed workers in Russia, Chem. Biol. Interact. 135–136 (2001) 487–503.
[11] M. Colonna, G. Laydevant, A cohort study of workers exposed to chloroprene in the department of Isere, France, Chem. Biol. Interact. 135–136 (2001) 505–514.
[12] IARC Monographs vol. 19, Chloroprene and polychloroprene, Lyon, France, 1979.
[13] IARC Monographs Suppl. 7, Chloroprene, Lyon, France, 1987.
[14] R. Melnick, R. Sills, C. Portier, J. Roycroft, B. Chou, S. Grumbein, R. Miller, Multiple organ carcinogenicity of inhaled chloroprene (2-chloro-1,3-butadiene) in F344/N rats and B6C3F1 mice and comparison of dose–response with 1,3-butadiene in mice, Carcinogenesis 20 (1999) 867–878.
[15] National Toxicology Program (NTP), Toxicology and carcinogenesis studies of chloroprene (CAS no. 126-99-8) in F344/N rats and B6C3F1 mice (inhalation studies), Technical Report no. 467, National Institutes of Health Publication no. 98-3957, National Institutes of Health, Bethesda, MD, 1998.
[16] IARC Monographs vol. 71, Chloroprene: re-evaluation of some organic chemicals, hydrazine and hydrogen peroxide, Lyon, France, 1999.
[17] N. Esmen, K. Kennedy, T. Hall, M. Phillips, Classification of worker exposures, Chem. Biol. Interact., 2006, doi:10.1016/j.cbi.2006.08.008, in press.
[18] N. Esmen, T. Hall, M. Phillips, G. Marsh, Chemical process based reconstruction of exposures for an epidemiological study. I. Theoretical and methodological issues, Chem. Biol. Interact., 2006, doi:10.1016/j.cbi.2006.08.009, in press.
[19] N. Esmen, T. Hall, M. Phillips, E. Jones, H. Basara, G. Marsh, J. Buchanich, Chemical process based reconstruction of exposures for an epidemiological study. II. Estimated exposures to chloroprene and vinyl chloride, Chem. Biol. Interact., 2006, doi:10.1016/j.cbi.2006.08.010, in press.
[20] T. Hall, N. Esmen, E. Jones, H. Basara, M. Phillips, G. Marsh, A. Youk, J. Buchanich, R. Leonard, Chemical process based reconstruction of exposures for an epidemiological study. III. Analysis of industrial hygiene samples, Chem. Biol. Interact., 2006, doi:10.1016/j.cbi.2006.09.004, in press.
[21] G. Marsh, A. Youk, J. Buchanich, M. Cunningham, N. Esmen, T. Hall, M. Phillips, Mortality patterns among industrial workers exposed to chloroprene and other substances. II. Mortality in relation to exposure, Chem. Biol. Interact., 2006, doi:10.1016/j.cbi.2006.08.012, in press.
[22] L. Schall, G. Marsh, V. Henderson, A two-stage protocol for verifying vital status in large historical cohort studies, J. Occup. Environ. Med. 39 (1997) 1097–1102.
[23] L. Schall, J. Buchanich, G. Marsh, G. Bittner, Utilizing multiple vital status tracing services optimizes mortality follow-up in large cohort studies, Ann. Epidemiol. 11 (2001) 292–296.
[24] J. Buchanich, D. Dolan, G. Marsh, J. Madrigano, Under ascertainment of deaths using social security records: a recommended solution to a little-known problem, Am. J. Epidemiol. 162 (2) (2005) 193–194.
[25] G. Marsh, A. Youk, R. Stone, S. Sefcik, C. Alcorn, OCMAP-PLUS, a new program for the comprehensive analysis of occupational cohort data, J. Occup. Environ. Med. 40 (1998) 351–362.
[26] G. Marsh, A. Youk, S. Sefcik, Mortality and Population Data System (MPDS), University of Pittsburgh, Department of Biostatistics technical report, 2005.
[27] N. Breslow, N. Day, The Design and Analysis of Cohort Studies. Statistical Methods in Cancer Research, vol. II, Oxford University Press, Lyon, 1987.
[28] MMWR November 6, 1998, State-specific prevalence among adults of current cigarette smoking and smokeless tobacco use and per capita tax-paid sales of cigarettes—United States, 47 (43), 1999, pp. 922–926.
[29] MMWR November 12, 2004, State-specific prevalence of current cigarette smoking among adults United States, 53 (44), 2003, pp. 1035–1037.
[30] J. Rice, P. Boffetta, 1,3-Butadiene, isoprene and chloroprene: reviews by the IARC monographs programme, outstanding issues, and research priorities in epidemiology, Chem. Biol. Interact. 135–136 (2001) 11–26.
[31] J. Acquavella, R. Leonard, A review of the epidemiology of 1,3-butadiene and chloroprene, Chem. Biol. Interact. 135–136 (2001) 43–52.
[32] IARC Monographs Suppl. 7, Vinyl chloride, Lyon, France, 1987.

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[33] H. Himmelstein, S. Carpenter, P. Hinderliter, Kinetic modeling of β-chloroprene metabolism. I. *In vitro* rates in liver and lung tissue fractions from mice, rats, hamsters, and humans, Toxicol. Sci. 79 (2004) 18–27.

[34] H. Himmelstein, S. Carpenter, M. Evans, P. Hinderliter, E. Kenyon, Kinetic modeling of β-chloroprene metabolism. II. The application of physiologically based modeling for cancer dose response analysis, Toxicol. Sci. 79 (2004) 28–37.

Please cite this article as: Gary M. Marsh et al., Mortality patterns among industrial workers exposed to chloroprene and other substances, Chemico-Biological Interactions (2006), doi:10.1016/j.cbi.2006.08.011

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Chemico-Biological Interactions xxx (2006) xxx–xxx
Chemico-Biological Interactions
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Mortality patterns among industrial workers exposed to chloroprene and other substances II. Mortality in relation to exposure

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Abstract

As part of an historical cohort study to investigate the mortality experience of industrial workers exposed to chloroprene (CD) and other substances, including vinyl chloride monomer (VC), we analyzed mortality from all cancers combined, respiratory system (RSC) and liver cancer in relation to CD and VC exposures. Subjects were 12,430 workers ever employed at one of two U.S. sites (Louisville, KY ($n=5507$) and Pontchartrain, LA ($n=1357$)) or two European sites (Maydown, Northern Ireland ($n=4849$) and Grenoble, France ($n=717$)).

Historical exposures for individual workers were estimated quantitatively for CD and VC. For sites L, M, P and G, respectively, average intensity of CD exposures (median value of exposed workers in ppm) were 5.23, 0.16, 0.028 and 0.149 and median cumulative exposures (ppm years) were 18.35, 0.084, 0.133 and 1.01. For sites L and M, respectively, average intensity of VC exposures (median value of exposed workers in ppm) was 1.54 and 0.03 and median cumulative exposures (ppm years) were 1.54 and 0.094.

We performed relative risk (RR) regression modeling to investigate the dependence of the internal cohort rates for all cancers combined, RSC and liver cancer on combinations of the categorical CD or VC exposure measures with adjustment for potential confounding factors. We categorized exposure measures into approximate quartiles based on the distribution of deaths from all cancers combined. We also considered 5- and 15-year lagged exposure measures and adjusted some RR models for worker pay type (white/blue collar) as a rough surrogate for lifetime smoking history. All modeling was site-specific to account for exposure heterogeneity. We also computed exposure category-specific standardized mortality ratios (SMRs) to assess absolute mortality rates.

With the exception of a one statistically significant association with duration of exposure to CD and all cancers combined in plant M, we observed no evidence of a positive association with all cancers, RSC or liver cancer and exposure to CD and/or VC using both the unlagged and lagged exposure measures: duration, average intensity or cumulative exposure to CD or VC; time since first CD or VC exposure; and duration of CD exposure or time since first CD exposure in presence or absence of VC exposure. We observed elevated and statistically significantly elevated RRs for some analysis subgroups, but these were due to inordinately low death rates in the baseline categories. With the possible exception of all cancer mortality in plant G, our additional adjustment of RRs for pay type revealed no evidence of positive confounding by smoking.

We conclude that exposures to CD or VC at the levels encountered in the four study sites do not elevate mortality risks from all cancers, RSC or liver cancer. This conclusion is corroborated by our analysis of general mortality patterns among the CD cohort

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0009-2797/$ – see front matter
doi:10.1016/j.cbi.2006.08.012

reported in our companion paper [G. Marsh, A. Youk, J. Buchanich, M. Cunningham, N. Esmen, T. Hall, M. Phillips, Mortality patterns among industrial workers exposed to chloroprene and other substances. I. General mortality patterns, Chem.-Biol. Interact., submitted for publication].

Keywords: Chloroprene; Cohort study; Liver cancer; Lung cancer; Mortality; Vinyl chloride; Exposure-response

1. Introduction

Chloroprene (2-chloro-1,3 butadiene) (CD) is a monomer used almost exclusively for the production of synthetic rubber and latexes [1]. The chemical structure of CD is similar to that of vinyl chloride, a known human carcinogen [2]. CD is classified by the International Agency for Research on Cancer as a possible human carcinogen (group 2B) based on sufficient evidence of carcinogenicity in experimental animals [3]. Epidemiological data on the carcinogenicity of CD are available from five cohort studies of chloroprene production workers in the U.S. [4], China [5], Armenia [6] and France [7], and the study of shoe manufacturing workers in Russia [8]. An increased risk of liver [5,6,8,9] and lung cancer [7] has been suggested by some of these studies. The inherent methodological limitations in the previous epidemiology studies raise questions; however, about their significance regarding human cancer risks [10,11].

To provide more definitive and comprehensive epidemiological evidence regarding the long-term health effects of exposure to CD, a four-plant, multi-national epidemiologic study of workers with potential exposure to CD was commissioned in 1999 by the International Institute of Synthetic Rubber Producers (IISRP). The exposure assessment component of the study was conducted at the University of Oklahoma (UOk) and the University of Illinois at Chicago (UIC); the epidemiology and biostatistics component was conducted at the University of Pittsburgh (UPitt). Our analysis of general mortality patterns among the CD cohort, reported in a companion paper [12], found no evidence of elevated mortality risks from any of the causes of death examined, including all cancers combined and lung and liver cancer, the sites of *a priori* interest. We report here the results of our detailed analysis of mortality from all cancers combined, lung and liver cancer in relation to quantitative measures of CD and VC exposure.

2. Methods

2.1. Study sites and subjects

The chloroprene (CD) cohort included all workers ($n = 12{,}430$) with potential CD exposure at one of four CD production sites from plant start-up date through the end of 2000 (1999 for one site). The sites include two DuPont/Dow Elastomers LLC (DDE) plants in the U.S. (Louisville, KY and Pontchartrain, LA), one DDE plant in Maydown, Northern Ireland (NI) and one Enichem Elastomers France plant in Grenoble, France (FR) (called here plants L, P, M and G). CD production dates for each plant were: L (1942–1972), P(1969-date), M (1960–1998) and G (1966-date). In two plants (L and M), CD production included an acetylene-based process that produced vinyl chloride (VC) as a by-product. Plant L made CD only through the acetylene process that was phased out in between 1971 and 1976; plant M made CD by the acetylene process from 1960 to 1980 then only by the butadiene process from 1980 to 1998. Plants P and G used only the butadiene process to produce CD. The newer butadiene process did not involve VC exposures and resulted in lower CD exposures for jobs related to monomer production than those associated with the early production years of the older plants L and M. Details of the CD cohort and the history, processes and chemical exposures associated with each study plant are described elsewhere [12–16].

2.2. Exposure estimation

2.2.1. Chemical process-based exposure reconstruction

Historical individual worker exposure profiles were estimated using a chemical process-based exposure reconstruction approach detailed elsewhere by Esmen et al. [13–15]. In brief, the exposure reconstruction was based on mathematical models which utilized exposure models based on the physics and chemistry associated with a given chemical process as determined from process documentation and task performance habits gleaned from interviews with knowledgeable plant personnel. The mathematical models used were based on the dispersion of the contaminant in the breathing zone of the worker performing the task associated with the exposure of interest. The simplest models scaled the contaminant vapor pressure by task execution time; more sophisticated models considered the contamination generation and dispersion rates. To the extent possible, all mathe-

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Table 1
Chloroprene (CD) and vinyl chloride (VC) exposure level classes

Level	CD (ppm)		VC (ppm)	
	Range	Nominal	Range	Nominal
0	$N < 0.0005$	0	$N < 0.01$	0
1	0.0005–0.005	0.0016	0.01–0.1	0.03
2	0.005–0.05	0.016	0.1–1	0.3
3	0.05–0.5	0.16	1–10	3
4	0.5–5	1.6	10+	16
5	5–50	16		
6	50–100	71		
7	100+	160		

N: negligible exposure.

matical models were validated with existing air monitoring data available for the later years (1975–1992). In comparison to the available exposure measurement data, the estimated exposure levels could have been obtained for many job categories using only the existing exposure measures leading to the same results obtained through modeling. This suggested that the exposure assignment in job categories with sparse or missing exposure measurement data was satisfactory.

2.2.2. *Estimated exposures to chloroprene and vinyl chloride*

In each plant, CD and VC exposures were modeled for all unique job title classes using six exposure classes for CD and four exposure classes for VC (Table 1). The width of the exposure classes (one order of magnitude) was calculated to minimize exposure misclassification on the basis of the specificity available in the job dictionary [13–15]. The nominal values (geometric mean of the associated class limits) of each agent were used as the daily average intensity value for a specific job with the associated exposure level. Exposures were estimated for the entire period of CD production in each plant. Although the four plants varied considerably with respect to the mix of production methods, CD exposures were remarkably similar in both estimated and measured values. CD exposures were found to be much more dependent on the improvement of the production methods, rather than deliberate reduction in exposures for occupational hygiene considerations. CD exposures were generally lower than the contemporaneous exposure limits or guidelines. Specifically, average CD exposures were less than 20 ppm in the pre-1960 era, less than 10 ppm in the 1960–1980 era, less than 1 ppm in the 1980–1990 era and less than 0.5 ppm thereafter. VC exposures, which occurred only in monomer production, were estimated to be relatively high in the pre-1960 era of CD production, but the highest exposures for the CD monomer operator job class did not exceed 2 ppm. For the same job class, VC exposures in the 1960–1970 era were less than 0.5 ppm.

2.2.3. *Construction of worker summary exposure measures*

For each plant, the job title classes and corresponding time-specific exposure class estimates for CD and VC were linked to the detailed subject work histories held by UPitt to enable the construction of working lifetime exposure profiles for each subject. These individual subject exposure profiles were used to compute three summary measures of CD and/or VC exposure for each subject as follows: duration of exposure (Dur) = the sum of the days spent in jobs with nonzero exposure to CD or VC (in years); cumulative exposure (Cum) = the product of the number of days in each job and the estimated average daily exposure to CD or VC (in ppm years); and average intensity of exposure (AIE) = the ratio of Cum to Dur (in ppm). The notation used to describe these summary measures is Agent_Measure, for example, CD_AIE refers to the average intensity of CD exposure.

We also considered a latent time-related exposure measure, time since first exposure to CD (or VC), expressed as Agent_TSFExp and constructed two composite summary measures, CD exposure in the presence of VC exposure (CDwVC_Measure) and CD exposure in the absence of VC exposure (CDwoVC_Measure). With the former composite measure, CD exposures are computed only for those jobs with concomitant VC exposure. Alternative characterizations of the CD and VC exposure measures described above were also computed using a lag period as described in detail by Youk et al. [17]. Simply put, the lag period refers to the fixed period of time before the time of observation during which exposures are not counted. Thus, with a 5-year lag period, exposures received up to five years before a given observation time are given zero weight, and exposures received five or more years before observation time are given full weight. Lagging attempts to characterize only the most etiologically relevant exposures and is particularly relevant for examining diseases, such as cancer, associated with long latent periods. We considered both a 5 and 15 years lag in our analysis of respiratory system cancer and liver cancer.

2.2.4. *Worker exposures to chloroprene and vinyl chloride*

Table 2 shows for each plant the distribution of subjects exposed to CD and/or VC. More than 92% of the workers at each plant were exposed to CD, with

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Table 2
Distribution of workers exposed to chloroprene and vinyl chloride

Plant	Number exposed (%)			Total subjects
	CD	VC	CD and VC	
Louisville	5468 (99.3)	1250 (22.7)	1250 (22.7)	5507
Maydown	4474 (92.3)	265 (5.5)	265 (5.5)	4849
Pontchartrain	1258 (92.7)	0 (0)	0 (0)	1357
Grenoble	717 (100.0)	0 (0)	0 (0)	717
All plants	11919 (95.9)	1515 (12.2)	1515 (12.2)	12430

Table 3
Summary statistics for chloroprene (CD) and vinyl chloride (VC) exposure measures by plant, exposed workers only

Exposure indicator	Louisville	Pontchartrain	Maydown	Grenoble
Chloroprene				
Person-years (total)	197919	30660	127036	17057
Person-years exposed	197034	26842	117640	17057
Person-years unexposed[a]	885	3818	9396	0
Duration (CD_Dur, years)				
25 percentile	0.997	3.08	0.003	5.71
Median	5.78	13.34	3.32	15.5
75 percentile	23.2	23.91	10.96	24.21
Maximum	45.2	30.998	42.5	33.996
Mean	12.15	14.12	7.11	15.51
Standard deviation	12.35	10.72	8.87	9.88
Coefficient of variation	101.6	75.91	124.8	63.74
Average intensity (CD_AIE, ppm)				
25 percentile	0.871	0.0016	0.0016	0.0160
Median	5.23	0.0283	0.160	0.149
75 percentile	16.00	0.552	1.60	1.39
Maximum	71.00	12.37	16.00	16.00
Mean	8.42	0.269	1.43	2.19
Standard deviation	10.40	0.552	3.27	4.54
Coefficient of variation	123.5	205.7	228.7	207.3
Cumulative (CD_Cum, ppm-years)				
25 percentile	1.52	0.0088	0.0022	0.0690
Median	18.35	0.133	0.0837	1.005
75 percentile	106.3	13.13	7.33	19.38
Maximum	1351.5	110.9	357.3	458.7
Mean	80.35	5.64	11.1	37.04
Standard deviation	134.9	10.33	32.79	85.93
Coefficient of variation	167.9	183.1	295.4	231.96
Vinyl chloride				
Person-years (total)	197919	n/a	127036	n/a
Person-years exposed	50401		8792	
Person-years unexposed[a]	147518		118244	
Duration (VC_Dur, years)				
25 percentile	0.392	n/a	0.296	n/a
Median	2.55		2.24	
75 percentile	12.39		5.57	
Maximum	29.42		27.23	
Mean	6.795		3.94	
Standard deviation	7.97		4.75	
Coefficient of variation	117.3		120.5	

Please cite this article as: Gary M. Marsh et al., Mortality patterns among industrial workers exposed to chloroprene and other substances, Chemico-Biological Interactions (2006), doi:10.1016/j.cbi.2006.08.012

Table 3 (*Continued*)

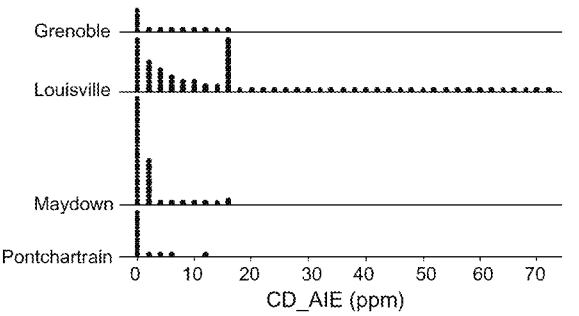
Exposure indicator	Louisville	Pontchartrain	Maydown	Grenoble
Average intensity (VC_AIE, ppm)				
25 percentile	0.265	n/a	0.030	n/a
Median	1.54		0.030	
75 percentile	3.00		0.030	
Maximum	3.00		0.300	
Mean	1.50		0.0648	
Standard deviation	1.26		0.0787	
Coefficient of variation	83.7		121.4	
Cumulative (VC_Cum, ppm-years)				
25 percentile	0.331	n/a	0.0089	n/a
Median	1.54		0.0941	
75 percentile	9.25		0.212	
Maximum	58.04		5.34	
Mean	8.66		0.335	
Standard deviation	13.55		0.672	
Coefficient of variation	156.4		200.8	

[a] Includes unexposed portion of person-years among subjects ultimately exposed.

99% of the Louisville workers exposed and all Grenoble workers exposed. Exposure to VC occurred only in plants L and M with 22.7 and 5.5% of subjects exposed, respectively. By nature of the production process involved, all workers exposed to VC were also exposed to CD.

Table 3 shows selected summary statistics for CD and VC exposures in each study plant. For each plant, the bulk of the accumulated person-years occurred during periods of exposure to CD. The median CD_Dur computed across individual workers ranged from 3.32 years at plant M to 15.5 years at plant G; the median CD_AIE ranged from 0.028 ppm (plant P) to 5.23 ppm (plant L) and the median CD_Cum ranged from 0.084 ppm years (plant M) to 18.35 ppm years (plant L). The median VC_Dur, VC_AIE and VC_Cum values for plants L and M were, respectively, 2.55 and 2.24 years, 1.54 and 0.03 ppm and 1.54 and 0.094 ppm years. For both CD and VC, the corresponding means of the three exposure measures were considerably greater than the medians, reflecting the positive skewness of the subjects' exposure distributions.

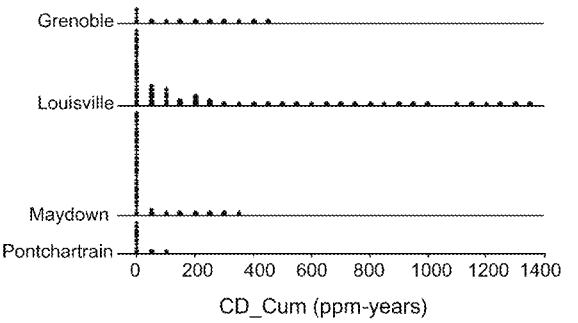
Figs. 1 and 2 provide plant-specific dot plots of the individual worker values for CD_AIE and CD_Cum; Figs. 3 and 4 provide corresponding dot plots for VC. The clustering of points at various levels of CD_AIE and VC_AIE corresponds with the nominal exposure values shown in Table 1. The figures show that plant L had, by far, the largest exposures to both CD and VC, due to its earlier period of operation and use of the acetylene process. Figs. 5 and 6 show for plants L and M, respectively, scattergrams of individual worker values of



Exposed workers only, each dot represents up to 62 subjects.

Fig. 1. Average intensity of chloroprene exposure by plant.

CD_AIE by VC_AIE. These are relevant to the composite exposure measures CDwVC_AIE and CDwoVC_AIE described above. The figures show that the CD_AIE and VC_AIE values were essentially uncorrelated.



Exposed workers only, each dot represents up to 84 subjects.

Fig. 2. Cumulative chloroprene exposure by plant.

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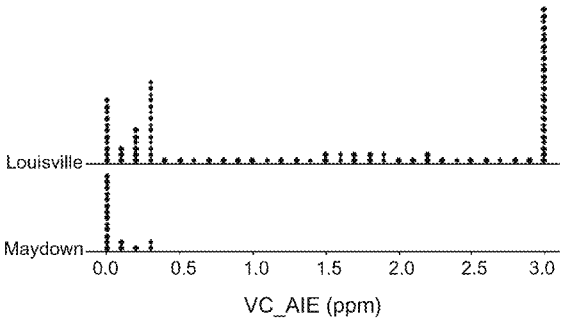

Fig. 3. Average intensity of vinyl chloride exposure by plant.

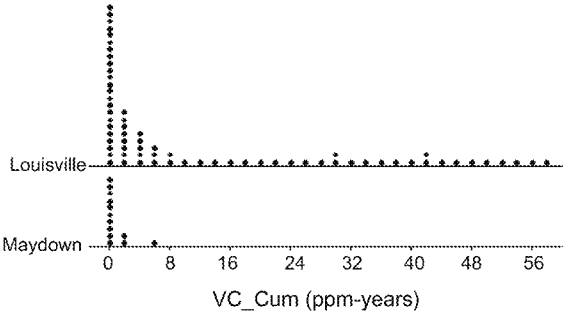

Fig. 4. Cumulative vinyl chloride exposure by plant.

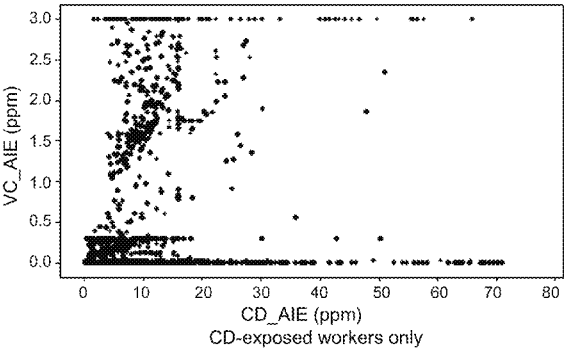

Fig. 5. Louisville plant, VC_AIE by CD_AIE.

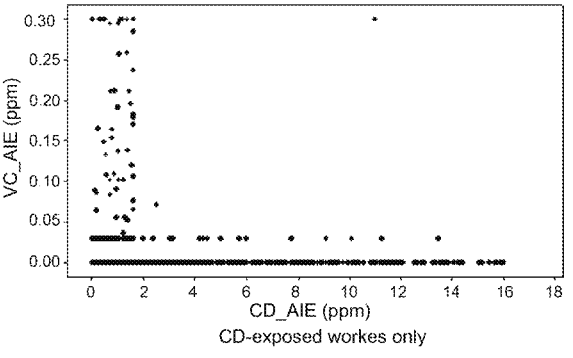

Fig. 6. Maydown plant, VC_AIE by CD_AIE.

2.3. Statistical analyses

2.3.1. Exposure-response based on internal comparisons

We used relative risk (RR) regression modeling to investigate the dependence of the internal cohort rates (modeled as time to death) for all cancers combined, respiratory system cancer (RSC) and liver cancer (categorized as "cancer of the biliary passages and liver" [12]) on combinations of the various CD and VC exposure measures, with adjustment for potential confounding factors. In our analysis of all cancers combined (each plant) and respiratory system cancer (plant L only), we also included adjustment for worker pay type, which was dichotomized as blue collar or white collar and analyzed as a time-dependent variable. The worker pay type variable was constructed by two of the authors (NE and TH) from detailed work history data for use in our exposure-response analysis for respiratory system cancer as a rough surrogate of education and socioeconomic status, which are highly correlated with smoking prevalence in both the U.S. and Europe [18]. In our analysis of general mortality patterns among the CD cohort reported elsewhere [12], we observed SMRs for all cancers combined and RSC were generally higher among blue collar workers, giving this variable the potential to confound exposure-response associations.

We categorized all exposure measures *a priori* into approximate quartiles based on the distribution of deaths from all cancer. The equal subgroup sizes approximately balance the precision of the risk estimates across subgroups; the use of the all cancer category standardizes comparability across cause of death categories and produces nearly equal subgroup sizes for many of the cause of death categories examined. We analyzed no alternative categorizations. For each cause of death, risk sets were explicitly constructed from the cohort data file with age as the primary time dimension, using the RISKSET program module in OCMAP-PLUS [19]. Risk sets were matched further on year of birth to control for cohort effects, and time-dependent exposures and the time-dependent variable, worker pay type, were evaluated for each individual at each event time they were at risk. Multiplicative relative risk models of the form $\lambda(t) = \lambda_0(t)\exp\{x(t)\beta\}$ were fit to the internal cohort rates [20,21], and the stratified conditional logistic regression programs in Stata [22] were used to estimate β from the explicitly constructed risk sets. For plants with less than 20 deaths for the causes of interest, the stratified exact conditional logistic regression program in LogXact was used to estimate β [23]. To parallel the descriptive SMR analysis of mortality in relation to exposure

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(described below), categorized forms of the covariates were considered. Demographic and exposure variables were first considered univariately as categorical variables to identify patterns of univariate associations with outcome variables and possible sparse data problems. Possible exposure-response associations were then evaluated with a forward stepwise approach to adjust for possible confounders. Effect modification was assessed if warranted by the main effects.

We assessed the statistical significance of each main effect (expressed as a global p-value) with a likelihood ratio statistic. For the exposure variables that exhibited a monotonic increasing or decreasing pattern in the parameter estimates, we conducted a test for linear trend (expressed as a trend p-value). All tests on RRs were done at the 0.05 significance level and no adjustment was made for multiple comparisons. All modeling was plant-specific to account for the marked heterogeneity in CD and VC exposures and other large disparities (e.g., vital records systems, time periods, culture, ethnicity, etc.) across the two U.S. and two European study plants. Models for liver cancer were limited by small numbers of deaths.

2.3.2. *Exposure-response based on external comparisons*

Mortality excesses and deficits in relation to CD and VC exposure levels were also determined via external mortality comparisons expressed as standardized mortality ratios (SMRs) along with their 95% confidence intervals (CI). The methods used to compute SMRs for the CD cohort study are described in detail elsewhere [12]. SMRs were computed for the categories of the CD and VC exposure measures used in the RR analysis described above. Person-year counts in the unexposed baseline categories included the observation time of workers prior to their first exposure. Statistically significant deviations of the SMRs below and above 1.00 were identified using Poisson probabilities [24]. All tests were done at the 0.05 significance level and no adjustment was made for multiple comparisons.

3. Results

Tables 4–8 show for plants L, M, P and G, respectively, the results of our exposure-response analyses based on internal and external comparisons. Results for the internal comparisons include for each category of the exposure measures considered, the number of observed deaths (cases) and associated non-cases summed across individual risk sets. The external comparisons include the number of person-years accumulated in each exposure category. For plant L (Table 4), none of the exposure measures was positively associated with mortality from all cancers combined or RSC using either internal or external comparisons. RRs fluctuate sporadically around 1.00 and the corresponding SMRs are consistently less than 1.00 and almost always statistically significant. For liver cancer, we observed elevated RRs in all non-baseline categories of each exposure measure. However, none of the RRs was statistically significant and there was no evidence of a positive association with any exposure measure. The elevated RRs result mainly from the exceedingly low death rates associated with the baseline categories of each measure, as reflected by the correspondingly low SMRs (i.e., the RR for a given non-baseline category is roughly related to the ratio of the corresponding SMR for that category to the SMR for the baseline category).

For plant M (Table 5), we observed a statistically significant positive association with CD_Dur and all cancers combined based on RRs and the associated non-baseline RRs were statistically significant (RRs = 1.53 (95% CI = 1.00–2.34) and 1.78 (95% CI = 1.11–2.84) for CD_Dur 10–19 and 20+ years, respectively, trend $p = 0.007$). However, as noted for liver cancer in Table 4, the elevated RRs and positive association with CD_Dur appear to be due mainly to an inordinately low death rate associated with the baseline category, as reflected by corresponding statistically significant SMR of 0.53 (95% CI = 0.41–0.67). In fact, both elevated RRs for CD_Dur arise as the ratio of death rates that are less than those of the corresponding external standard population (i.e., SMR = 0.85 and 0.97 for CD_Dur 10–19 and 20+ years, respectively). There is no evidence in Table 5 of a positive association with all cancers combined and the other exposure measures considered, and the corresponding SMRs are consistently less than 1.00. For RSC, we observed some limited evidence of a positive association with CD_AIE and CD_Cum along with a marginally statistically significant ($0.05 < p < 0.10$) trend test for CD_AIE, however, this appears again to be driven by inordinately low baseline death rates for both exposure measures as reflected by the statistically significant baseline SMRs (SMR for baseline CD_AIE = 0.47 (95% CI = 0.23–0.83) and SMR for baseline CD_Cum = 0.54 (95% CI = 0.29–0.90)).

For plants P and G (Tables 6 and 7), the evaluation of exposure-response was made more difficult by the smaller numbers of observed deaths, particularly for RSC. In plant P (Table 6), none of the exposure measures was positively associated with mortality from all cancers combined or RSC using either internal or external comparisons. We observed one statistically significant

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Table 4
Exposure-response analysis for chloroprene and selected cancer sites by exposure metric, Louisville plant, relative risks (RR) and standardized mortality ratios (SMR)

Metric[a]	Deaths	Internal rate analysis			External rate analysis[b]	
		Noncases[c]	RR[d] (95% CI)	*p*-Value	Person-years[e]	SMR (95% CI)
All cancer combined						
CD_Dur						
<10	326	60363	1.00	Global = 0.71	131276	0.70** (0.63–0.78)
10–19	64	9559	1.06 (0.80–1.41)	Trend = 0.42	30404	0.68** (0.53–0.87)
20+	262	39856	1.07 (0.90–1.27)		36239	0.82** (0.72–0.93)
CD_AIE						
<3.6216	163	29840	1.00	Global = 0.27	69274	0.73** (0.62–0.83)
3.6216–8.1245	163	22373	1.19 (0.94–1.50)	Trend = 0.97	27933	0.88 (0.75–1.02)
8.1246–15.99	97	16147	0.93 (0.71–1.21)		28689	0.65** (0.53–0.79)
16.0+	229	40418	1.07 (0.86–1.32)		72023	0.72** (0.63–0.82)
CD_Cum						
<4.747	163	30338	1.00	Global = 0.35	68918	0.75** (0.64–0.87)
4.747–55.918	163	29222	0.98 (0.78–1.23)	Trend = 0.83	56737	0.71** (0.60–0.82)
55.919–164.052	163	24222	1.14 (0.91–1.43)		39840	0.79** (0.68–0.92)
164.053+	163	24996	0.93 (0.73–1.17)		32424	0.70** (0.60–0.82)
Respiratory system cancer						
CD_Dur						
<10	137	25995	1.00	Global = 0.98	131276	0.74** (0.62–0.87)
10–19	23	3806	0.98 (0.62–1.57)	Trend = 0.84	30404	0.66** (0.42–0.99)
20+	106	17174	0.97 (0.75–1.27)		36239	0.79* (0.65–0.96)
CD_AIE						
<3.6216	56	12642	1.00	Global = 0.06	69274	0.63** (0.48–0.82)
3.6216–8.1245	70	9812	1.34 (0.93–1.95)	Trend = 0.20	27933	0.90 (0.70–1.14)
8.1246–15.99	33	6950	0.88 (0.56–1.38)		28689	0.56** (0.38–0.78)
16.0+	107	17571	1.36 (0.97–1.91)		72023	0.83 (0.68–1.00)
CD_Cum						
<4.747	62	12961	1.00	Global = 0.07	68918	0.71** (0.55–0.91)
4.747–55.918	67	12656	1.00 (0.71–1.43)	Trend = 0.71	56737	0.71** (0.55–0.90)
55.919–164.052	77	10471	1.32 (0.94–1.88)		39840	0.92 (0.73–1.15)
164.053+	60	10887	0.85 (0.58–1.23)		32424	0.65** (0.50–0.84)
Liver cancer[f]						
CD_Dur						
<10	6	1500	1.00	Global = 0.24	131276	0.61 (0.22–1.32)
10–19	4	216	3.85 (0.76–17.09)	Trend = 0.36	30404	2.08 (0.57–5.33)
20+	7	965	1.75 (0.49–6.44)		36239	0.99 (0.40–2.04)
CD_AIE						
<3.6216	3	714	1.00	Global = 0.22	69274	0.62 (0.13–1.80)
3.6216–8.1245	7	568	3.81 (0.77–25.76)	Trend = 0.84	27933	1.73 (0.70–3.56)
8.1246–15.99	3	388	1.84 (0.22–15.74)		28689	0.94 (0.19–2.74)
16.0+	4	1011	1.31 (0.20–10.07)		72023	0.59 (0.16–1.52)
CD_Cum						
<4.747	2	744	1.00	Global = 0.17	68918	0.43 (0.05–1.55)
4.747–55.918	3	725	1.90 (0.21–23.81)	Trend = 0.09	56737	0.59 (0.12–1.74)
55.919–164.052	7	653	5.10 (0.88–54.64)		39840	1.62 (0.65–3.33)
164.053+	5	559	3.33 (0.48–39.26)		32424	1.00 (0.33–2.34)

[a] Categories based on approximate quartiles of all cancer deaths; decimal places of cutpoints reflect precision needed for computational purposes only and not precision of exposure assessment.
[b] Local county rates.
[c] The number of persons in decedent's risk set used in calculation of RR.
[d] Also adjusted for sex.
[e] The number of person-years used in calculation of SMR.
[f] Analyzed using LogXact.
* $p < 0.05$.
** $p < 0.01$.

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Table 5
Exposure-response analysis for chloroprene and selected cancer sites by exposure metric, Maydown plant, relative risks (RR) and standardized mortality ratios (SMR)

Metric[a]	Deaths	Internal rate analysis			External rate analysis[b]	
		Noncases[c]	RR[d] (95% CI)	*p*-Value	Person-years[e]	SMR (95% CI)
All cancers combined						
CD_Dur						
<10	66	9674	1.00	Global = 0.03	102413	0.53** (0.41–0.67)
10–19	35	2965	1.53* (1.00–2.34)	Trend = 0.007	17257	0.85 (0.59–1.18)
20+	27	2349	1.78* (1.11–2.84)		7366	0.97 (0.64–1.41)
CD_AIE						
<0.1538	43	5660	1.00	Global = 0.98	57453	0.54** (0.39–0.73)
0.1538–1.269	28	2931	1.02 (0.60–1.72)	Trend = 0.97	22489	0.83 (0.55–1.20)
1.270–1.69	36	3973	1.07 (0.67–1.71)		32973	0.70* (0.49–0.96)
1.70+	21	2424	0.95 (0.54–1.65)		14121	0.70 (0.43–1.07)
CD_Cum						
<0.0387	43	6062	1.00	Global = 0.92	63130	0.50** (0.36–0.67)
0.0387–6.7310	28	3266	1.12 (0.67–1.89)	Trend = 0.75	32527	0.74 (0.49–1.07)
6.7311–24.50	29	3065	0.94 (0.53–1.66)		19539	0.79 (0.53–1.13)
24.51+	28	2595	0.95 (0.53–1.70)		11840	0.85 (0.56–1.22)
Respiratory system cancer						
CD_Dur						
<10	28	3649	1.00	Global = 0.82	102413	0.73 (0.48–1.05)
10–19	12	1143	0.81 (0.36–1.79)	Trend = 0.84	17257	0.86 (0.44–1.50)
20+	8	992	1.17 (0.23–5.92)		7366	0.83 (0.36–1.64)
CD_AIE						
<0.1538	11	2180	1.00	Global = 0.08	57453	0.47** (0.23–0.83)
0.1538–1.269	12	1133	2.83* (1.09–7.38)	Trend = 0.09	22489	1.08 (0.56–1.89)
1.270–1.69	16	1522	2.63* (1.11–6.23)		32973	0.93 (0.53–1.51)
1.70+	9	949	2.23 (0.83–5.97)		14121	0.87 (0.40–1.65)
CD_Cum						
<0.0387	14	2300	1.00	Global = 0.39	63130	0.54* (0.29–0.90)
0.0387–6.7310	9	1263	1.65 (0.66–4.15)	Trend = 0.10	32527	0.74 (0.34–1.40)
6.7311–24.50	12	1181	1.89 (0.72–4.96)		19539	0.97 (0.50–1.69)
24.51+	13	1040	2.28 (0.86–6.01)		11840	1.13 (0.60–1.92)

[a] Categories based on approximate quartiles of all cancer deaths; decimal places of cutpoints reflect precision needed for computational purposes only and not precision of exposure assessment.
[b] National rates.
[c] The number of persons in decedent's risk set used in calculation of RR.
[d] Also adjusted for worker service type and duration of employment.
[e] The number of person-years used in calculation of SMR.
* $p < 0.05$.
** $p < 0.01$.

RR for all cancers combined in the second category of CD_AIE (RR = 4.76; 95% CI = 1.39–6.27); however, this appears to be an isolated finding. RRs for RSC were also elevated in all baseline categories of each exposure measure, again driven by the inordinately low baseline death rates (i.e., baseline SMRs for CD_Dur, CD_AIE and CD_Cum = 0.28 (95%CI = 0.03–1.00), 0.33 (95% CI = 0.09–0.85) and 0.40 (95% CI = 0.08–1.18), respectively. In plant G (Table 7), none of the exposure measures was positively associated with mortality from all cancers combined using either internal or external comparisons. There is some limited evidence of a positive association with CD_AIE and CD_Cum and RSC; however, the linear trends and the exposure category-specific RRs were not statistically significant. While the death rates for RSC associated with the baseline categories of CD_AIE and CD_Cum were not as low as those in the other plants, they were still about 25% less

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Table 6
Exposure-response analysis for chloroprene and selected cancer sites by exposure metric, Pontchartrain plant, relative risks (RR) and standardized mortality ratios (SMR)

Metric[a]	Deaths	Internal rate analysis			External rate analysis[b]	
		Noncases[c]	RR (95% CI)	*p*-Value	Person-years[d]	SMR (95% CI)
All cancers combined						
CD_Dur						
<10	15	2039	1.00	Global = 0.71	19067	0.75 (0.42–1.24)
10–19	12	2095	0.71 (0.32–1.58)	Trend = 0.56	7668	0.59 (0.31–1.03)
20+	7	1473	0.83 (0.27–2.53)		3926	0.57 (0.23–1.18)
CD_AIE						
<0.0017	17	2735	1.00	Global = 0.17	15858	0.55** (0.32–0.88)
0.0017–0.1329	4	298	4.76* (1.39–16.27)	Trend = 0.44	1574	2.76 (0.75–7.06)
0.1330–0.8174	7	1409	1.58 (0.57–4.37)		5522	0.76 (0.31–1.57)
0.8175+	6	1165	1.34 (0.49–3.65)		7707	0.69 (0.26–1.51)
CD_Cum						
<0.0193	15	1794	1.00	Global = 0.31	15354	0.75 (0.42–1.24)
0.0193–1.8944	6	1434	0.52 (0.20–1.37)	Trend = 0.91	6363	0.41* (0.15–0.90)
1.8945–16.1918	6	766	1.50 (0.55–4.11)		6027	1.07 (0.39–2.32)
16.1919+	7	1613	0.80 (0.29–2.16)		4916	0.61 (0.24–1.25)
Respiratory system cancer[e]						
CD_Dur						
<10	2	653	1.00	Global = 0.33	19067	0.28 (0.03–1.00)
10–19	7	799	3.08 (0.62–15.31)	Trend = 0.32	7668	0.85 (0.34–1.75)
20+	3	747	2.09 (0.26–16.85)		3926	0.60 (0.12–1.76)
CD_AIE						
<0.0017	4	932	1.00	Global = 0.25	15858	0.33* (0.09–0.85)
0.0017–0.1329	1	102	7.28 (0.09–167.13)	Trend = 0.14	1574	2.05 (0.05–11.44)
0.1330–0.8174	4	646	5.03 (0.59–58.02)		5522	1.11 (0.30–2.85)
0.8175+	3	519	3.50 (0.37–33.64)		7707	0.90 (0.19–2.62)
CD_Cum						
<0.0193	3	600	1.00	Global = 0.70	15354	0.40 (0.08–1.18)
0.0193–1.8944	3	468	1.60 (0.20–12.77)	Trend = 0.34	6363	0.52 (0.11–1.53)
1.8945–16.1918	2	322	2.90 (0.20–34.11)		6027	0.96 (0.12–3.48)
16.1919+	4	809	2.32 (0.30–21.83)		4916	0.85 (0.23–2.18)

[a] Categories based on approximate quartiles of all cancer deaths; decimal places of cutpoints reflect precision needed for computational purposes only and not precision of exposure assessment.
[b] Local county rates.
[c] The number of persons in decedent's risk set used in calculation of RR.
[d] The number of person-years used in calculation of SMR.
[e] Analyzed using LogXact.
* $p < 0.05$.
** $p < 0.01$.

than those in the external comparison populations (i.e., baseline SMRs for CD_AIE and CD_Cum were 0.76 and 0.72, respectively). As noted for the other plants, the low baseline rates at least partly explain the elevated RRs for many of the non-baseline categories.

Table 8 shows our exposure-response analyses for VC that was limited to plant L. For all cancers combined and RSC, deficits in deaths based on RRs and SMRs were observed in all exposure categories; many were statistically significant. Fifteen of the 17 liver cancer deaths in plant L occurred among unexposed workers; RRs and SMRs in the non-baseline categories were unremarkable.

While not shown, our analysis of mortality among plant L and M workers in relation to the four composite exposure measures, CDwVC_AIE, CDwVC_Cum, CDwoVC_AIE and CDwoVC_Cum, produced risk estimates similar to those based on the marginal CD exposure measures (i.e., exposure to CD regardless of VC exposure) and none of the composite measures revealed evidence of increasing cancer risks with increasing expo-

Please cite this article as: Gary M. Marsh et al., Mortality patterns among industrial workers exposed to chloroprene and other substances, Chemico-Biological Interactions (2006), doi:10.1016/j.cbi.2006.08.012

Table 7
Exposure-response analysis for chloroprene and selected cancer sites by exposure metric, Grenoble plant, relative risks (RR) and standardized mortality ratios (SMR)

Metric[a]	Deaths	Internal rate analysis			External rate analysis[b]	
		Noncases[c]	RR (95% CI)	*p*-Value	Person-years[d]	SMR (95% CI)
All cancers combined						
CD_Dur						
<10	9	934	1.00	Global = 0.43	9813	0.63 (0.29–1.20)
10–19	5	819	0.60 (0.20–1.80)	Trend = 0.82	4900	0.40* (0.13–0.94)
20+	6	585	1.32 (0.43–4.08)		2344	0.83 (0.31–1.82)
CD_AIE						
<0.0051	5	551	1.00	Global = 0.99	3393	0.60 (0.20–1.41)
0.0051–0.0880	5	477	1.21 (0.35–4.22)	Trend = 0.95	4694	0.55 (0.18–1.28)
0.0881–1.2246	5	616	1.21 (0.34–4.40)		3189	0.67 (0.22–1.56)
1.2247+	5	694	1.04 (0.29–3.76)		5781	0.56 (0.18–1.31)
CD_Cum						
<0.0497	5	584	1.00	Global = 0.92	4267	0.56 (0.18–1.31)
0.0497–1.4149	5	532	1.16 (0.33–4.08)	Trend = 0.57	4749	0.53 (0.17–1.23)
1.4150–23.9306	5	683	1.07 (0.30–3.84)		4619	0.55 (0.18–1.28)
23.9307+	5	539	1.54 (0.43–5.60)		3422	0.79 (0.26–1.85)
Respiratory system cancer[e]						
CD_Dur						
<10	3	500	1.00	Global = 0.70	9813	0.64 (0.13–1.87)
10–19	5	448	1.84 (0.44–7.77)	Trend = 0.58	4900	1.16 (0.38–2.71)
20+	2	272	1.46 (0.22–9.61)		2344	0.71 (0.09–2.58)
CD_AIE						
<0.0051	2	294	1.00	Global = 0.45	3393	0.76 (0.09–2.80)
0.0051–0.0880	1	260	0.63 (0.06–6.96)	Trend = 0.19	4694	0.32 (0.01–1.76)
0.0881–1.2246	3	325	2.29 (0.22–34.16)		3189	1.06 (0.22–3.09)
1.2247+	4	341	2.99 (0.36–41.87)		5781	1.25 (0.34–3.19)
CD_Cum						
<0.0497	2	312	1.00	Global = 0.40	4267	0.72 (0.09–2.61)
0.0497–1.4149	1	288	0.61 (0.05–6.76)	Trend = 0.17	4749	0.30 (0.01–1.69)
1.4150–23.9306	4	356	2.87 (0.35–39.70)		4619	1.19 (0.32–3.04)
23.9307+	3	264	3.14 (0.30–47.99)		3422	1.28 (0.26–3.73)

[a] Categories based on approximate quartiles of all cancer deaths; decimal places of cutpoints reflect precision needed for computational purposes only and not precision of exposure assessment.
[b] National rates.
[c] The number of persons in decedent's risk set used in calculation of RR.
[d] The number of person-years used in calculation of SMR.
[e] Analyzed using LogXact.
* $p < 0.05$.

sure. Also not shown, our analyses of RSC and liver cancer mortality in relation to 5 and 15 year lagged measures of CD_Dur, CD_AIE and CD_Cum did not materially alter the findings from the unlagged analyses. Likewise, for RSC and liver cancer, we observed no evidence of an association with time since first exposure to CD or to VC (not shown).

We attempted to roughly additionally adjust RRs for RSC for potential confounding by smoking, via the surrogate variable worker pay type (blue/white collar). Because of the small number of white-collar RSC deaths among the white-collar workers in each plant (3, 0, 2 and 0 white collar RSC deaths for plants L, M, P and G, respectively), the adjusted analysis was limited to plant L. For all cancers combined, additional adjustment for potential confounding by worker pay type had little effect on the all cancer RRs for either CD_AIE or CD_Cum. For plant P, additionally adjusted RRs were higher for all exposure categories of both measures, suggesting negative confounding by smoking; for plant G,

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Table 8
Exposure-response analysis for vinyl chloride monomer and selected cancer sites by exposure metric, Louisville plant, relative risks (RR) and standardized mortality ratios (SMR)

Metric[a]	Deaths	Internal rate analysis			External rate analysis[b]	
		Noncases[c]	RR[d] (95% CI)	p-Value	Person-years[e]	SMR (95% CI)
All cancers combined						
VC_Dur						
Unexposed	524	77268	1.00	Global = 0.0002	147518	0.80** (0.73–0.87)
>0–5	71	17509	0.66* (0.52–0.84)	Trend = 0.0001	31911	0.58** (0.45–0.73)
5–9	9	2444	0.78 (0.55–1.11)		6122	0.47* (0.21–0.88)
10+	48	11557	0.50* (0.29–0.85)		12369	0.60** (0.18–0.61)
VCM_AIE						
Unexposed	524	77268	1.00	Global = 0.0004	147518	0.80** (0.73–0.87)
>0–0.27	32	6335	0.80 (0.56–1.15)	Trend = 0.0001	10880	0.71 (0.49–1.00)
0.28–1.75	34	9312	0.59* (0.41–0.83)		14543	0.52** (0.36–0.73)
1.751–2.99	15	4087	0.56* (0.35–0.87)		5768	0.46** (0.26–0.76)
3.0+	47	11776	0.70* (0.51–0.97)		19210	0.47** (0.35–0.63)
VCM_Cum						
Unexposed	524	77268	1.00	Global = 0.0004	147518	0.80** (0.73–0.87)
>0–0.4476	32	7057	0.72 (0.50–1.03)	Trend < 0.0001	14506	0.63** (0.43–0.89)
0.4477–1.9482	32	6747	0.82 (0.57–1.18)		11583	0.58** (0.39–0.81)
1.9483–14.5832	32	9578	0.57* (0.40–0.82)		14267	0.44** (0.30–0.62)
14.5833+	32	8128	0.60* (0.42–0.86)		10045	0.53** (0.36–0.75)
Respiratory system cancer						
VC_Dur						
Unexposed	232	33132	1.00	Global < 0.0001	147518	0.89 (0.78–1.02)
>0–5	20	8732	0.38* (0.24–0.59)	Trend < 0.0001	31911	0.38** (0.23–0.59)
5–9	2	3313	0.48* (0.25–0.90)		6122	0.25* (0.03–0.89)
10+	12	1798	0.15* (0.04–0.60)		12369	0.35** (0.18–0.61)
VCM_AIE						
Unexposed	232	33132	1.00	Global < 0.0001	147518	0.89 (0.78–1.02)
>0–0.27	12	2743	0.64 (0.35-1.15)	Trend < 0.0001	10880	0.62 (0.31–1.08)
0.28–1.75	6	4035	0.22* (0.10–0.50)		14543	0.22** (0.08–0.47)
1.751–2.99	3	2443	0.23* (0.09–0.62)		5768	0.22** (0.05–0.65)
3.0+	13	4622	0.41* (0.23–0.73)		19210	0.31** (0.16–0.53)
VCM_Cum						
Unexposed	232	33132	1.00	Global < 0.0001	147518	0.89 (0.78–1.02)
>0–0.4476	13	3009	0.64 (0.36–1.12)	Trend < 0.0001	14506	0.60 (0.32–1.02)
0.4477–1.9482	8	2964	0.42* (0.21–0.86)		11583	0.34** (0.15–0.67)
1.9483–14.5832	6	4232	0.22* (0.10–0.49)		14267	0.19** (0.07–0.42)
14.5833+	7	3638	0.27* (0.13–0.58)		10045	0.27** (0.11–0.57)
Liver cancer[f]						
VC_Dur						
Unexposed	15	1952	1.00	Global = 0.24	147518	1.07 (0.60–1.77)
>0–5	1	407	2.49[g] (0.41–∞)	Trend = 0.23	31911	0.37 (0.01–2.08)
5–9	1	61	0.69[g] (0.02-∞)		6122	2.38 (0.06–13.29)
10+	0	261	3.96[g] (0.10-∞)		12369	–(0–2.05)
VCM_AIE						
Unexposed	15	1952	1.00	Global = 0.46	147518	1.07 (0.60–1.77)
>0–0.27	1	139	1.04 (0.02–7.04)	Trend = 0.20	10880	0.98 (0.03–5.48)
0.28–1.75	0	223	0.49[g] (−∞, 2.98)		14543	–(0–2.59)
1.751+	1	367	0.43 (0.01–2.92)		24978	0.37 (0.01–2.04)
VCM_Cum						
Unexposed	15	1952	1.00	Global = 0.54	147518	1.07 (0.60–1.77)

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Table 8 (*Continued*)

Metric[a]	Deaths	Internal rate analysis			External rate analysis[b]	
		Noncases[c]	RR[d] (95% CI)	*p*-Value	Person-years[e]	SMR (95% CI)
>0–0.4476	0	164	0.66[g] (-∞,4.00)	Trend = 0.31	14506	–(0–3.25)
0.4477–1.9482	1	168	0.97 (0.02–6.67)		11583	0.86 (0.02–4.79)
1.9483+	1	397	0.38 (0.01–2.58)		24312	0.36 (0.01–1.99)

[a] Categories based on approximate quartiles of all cancer deaths; decimal places of cutpoints reflect precision needed for computational purposes only and not precision of exposure assessment.
[b] Local county rates.
[c] The number of persons in decedent's risk set used in calculation of RR.
[d] Also adjusted for sex.
[e] The number of person-years used in calculation of SMR.
[f] Analyzed using LogXact.
[g] Median-unbiased estimate.
* $p < 0.05$.
** $p < 0.01$.

the opposite pattern emerged, suggesting positive confounding by smoking. In neither case; however, did the additional adjustment for worker pay type materially alter the unadjusted findings of no association with either exposure measure. In plant L, additional adjustment for pay type had little effect on the RSC RRs for CD_AIE or CD_Cum (data not shown).

4. Discussion and conclusions

As described in detail in our analysis of general mortality patterns [12], our historical cohort study of workers from four CD production sites in the U.S. and Europe represents the largest and the most comprehensive and rigorous investigation of the long-term health effects of exposure to CD conducted to date. It overcomes most of the shortcomings and uncertainties noted by Rice and Bofetta [10] and Acquavella and Leonard [11] that have limited the interpretation of findings from the five available cohort studies [4–8]. A particular strength of our study was the rigorous, chemical process-based exposure reconstruction for chloroprene and vinyl chloride conducted by Esmen et al. [13–15] and Hall et al. [16] that enable us to examine mortality from all cancers combined and from the *a priori* sites of interest, lung and liver cancer, in relation to several quantitative measures of CD and/or VC exposure.

Another strength of our exposure-response analyses was the use of national and local county mortality comparisons and robust statistical modeling of internal cohort rates. The strengths of the internal study group comparison are that it will usually reduce the healthy worker effect [25], and it allows direct comparison of relative risk across strata. However, internal comparisons can be unstable when the study population is small and/or the disease under study is rare (producing wider confidence limits), and may be misleading if workers included in the baseline category (i.e., least exposed) have different underlying cancer risks than workers in the exposed groups. On the other hand, external comparisons based on regional rates have the strengths of being able to adjust for geographic variability in social, cultural and economic factors related to disease [26] and are generally very stable. The disadvantages of the external comparison group are an inability to adjust for the healthy worker effect and a difficulty in comparing standardized mortality ratios between groups when their confounder distributions differ [27].

When we used external comparisons of the surrounding county populations of each study plant, we observed many deficits in death from all cancers combined, RSC and liver cancer that were often largest among the unexposed workers, but still present among workers in the non-baseline exposure categories. This pattern of findings by exposure category in the external population-based SMRs led to elevated relative rates (RRs) of disease when rates for non-baseline categories were compared to the baseline (unexposed) rates. For example, for RSC by CD_AIE in plant P (Table 6), an RR of 3.50 (95%CI = 0.37–33.64) for the highest exposure category (0.8175+ ppm), or an apparent 3.5-fold excess, results because a small 10% deficit in deaths in the highest exposure category (SMR = 0.90; 95% CI = 0.19–2.62) is essentially being compared to a exceedingly large, statistically significant 67% deficit in the baseline category (SMR = 0.33; 95%CI = 0.09–0.85). Thus, the question arises as to whether the ratio of small to large deficits in deaths (essentially, but not exactly, what is expressed

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via RRs) should be interpreted as a meaningful "excess" in deaths. This enigmatic feature of exposure-response analyses created by inordinately low baseline rates has been observed in other major occupational cohort studies, such as the cohort studies of formaldehyde [28–30] and acrylonitrile [31] workers conducted by the National Cancer Institute, and has stimulated reanalyses and reinterpretation of the NCI cohort data [32–34]. Although RRs for the cancer sites and exposure measures considered were elevated in many non-baseline categories due to the low baseline rates, we observed no consistent evidence that RRs were positively associated with increasing exposure in any of the study plants.

There are at least two possible explanations for the large differences in the cancer relative risks in the CD cohort when internal or external comparison rates are used. The first is that internal comparisons produce more valid results because selection bias stemming from the "healthy worker effect" can reduce the putative effect of high exposure to CD (or VC) when external comparison rates are used. The healthy worker effect is evident in this population by the low relative risks for all causes of death for CD-exposed (SMR = 0.71; 95% CI = 0.69–0.73) and CD-unexposed workers (SMR = 0.88; 95% CI = 0.69–1.10). However, the selection for workers who are healthy at time of hire is usually more relevant for cardiovascular and nonmalignant respiratory diseases than lung cancer, which has a relatively sudden onset, short survival time and high case-fatality rate [35].

A second explanation is that the external comparisons produce more valid results because the unexposed group has a different underlying cancer risk than the exposed group. As shown above, the risk in the highest exposure category when internal comparisons are used may simply be the result of an unusually low lung cancer death rate among workers in the unexposed baseline category. In fact, had the death rates for all cancer, RSC or liver cancer among the unexposed workers been closer to or equal to those of the general regional populations from which the four plant workforces were drawn, the internal RRs calculated for quartiles of CD (or VC) exposure across the total cohort would probably have been uniformly near or less than 1.00.

The very low SMRs for all cancer, lung and liver cancer, especially among unexposed workers, are puzzling given that we used regional standard population rates. Although a small percentage of deaths (estimated at about 5%) may have been missed among transferees in plant P and among subjects who emigrated in plants M and G [12], under-ascertainment of deaths is an unlikely explanation for these low SMRs. Also, because regional rates can help adjust for the social, cultural and economic factors related to diseases such as lung cancer, and even help to adjust for geographic variability in tobacco use [26], it is difficult to postulate what non-occupational factors may have had such a profound influence on the cancer mortality experience of this cohort. It was hoped that our additional model adjustment for worker pay type, a correlate of education/socioeconomic status, and thus, smoking history, might help to explain the inordinately low and often statistically significant baseline SMRs for all cancers combined and RSC found for each study plant in the baseline categories of each exposure measure. For example, if subjects at risk in the baseline exposure categories were lighter smokers than subjects at risk in the non-baseline categories, this would negatively confound baseline SMRs for RSC relative to non-baseline SMRs and positively confound the corresponding non-baseline RRs. To a lesser extent, the same pattern could occur for all cancers combined. However, with the possible exception of plant G, where pay type-adjusted RRs for all cancers combined were uniformly less, suggesting positive confounding by smoking, the additional adjustment for worker pay type did not materially alter the pattern of RRs for all cancer and RSC found in the unadjusted models.

With the possible exception of liver cancer in plant L (based on small numbers of death), chance alone does not appear to be an explanation for the cancer deficits observed among unexposed workers in this study. Our U.S. and regional rate-based SMRs (and RRs) for all cancers and RSC in all categories of the CD exposures examined were based on sufficiently large numbers of observed deaths to provide stable risk estimates, and deficits were generally consistent across the CD exposure categories considered. Also, the general quality of the follow-up and cause of death ascertainment in this study rule out under-ascertainment of cancer deaths as a reason for the deficits. Given the absence of a viable explanation derived from the available study data, what remains is the possibility that some heretofore unknown selection factors for low cancer incidence or mortality were operating on the unexposed subjects in this cohort, or that some type of protective effect for lung cancer arose from a particular exposure or combination of exposures encountered at the study plants. Without further formal investigation of this phenomenon in the CD cohort, the reason(s) for the marked deficits in cancer in unexposed workers will remain unknown.

While the possible occurrence of the rare VC-related cancer, angiosarcoma of the liver, was of interest in this study, methodological limitations precluded a full

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evaluation. A full account of our evaluation of angiosarcoma was provided in our companion paper [12]. In brief, because angiosarcoma of the liver does not have a specific ICD code until the 10th revision (1999+), it can only be roughly identified in earlier revisions by manually reviewing text fields of death certificates. A comprehensive death certificate review was not possible in this study as we obtained death certificates for the two U.S. plants only for deaths that occurred before the National Death Index (before 1979) and in some cases cause of death for pre-1979 deaths was obtained as an ICD code from the DuPont mortality registry. For plant G we obtained ICD codes only from our French collaborators and in plant M we obtained only a limited number of death certificates. These limitations notwithstanding, "angiosarcoma of the liver" was not mentioned on any death certificates available for our review.

In summary, our analysis of the cancer mortality experience of the CD cohort provides no evidence that exposure to CD or VC, at the levels encountered in the four study plants, increases the risk of death from all cancers or the sites of *a priori* interest, lung (included within the broader category respiratory system cancer) and liver (categorized as "cancer of the biliary passages and liver"). Our findings based on external comparisons using regional rates produced exposure category-specific risks very different than those based on internal rates due largely to inordinately low death rates among workers in the unexposed categories. We conclude that chance or selection bias in the form of the healthy worker effect were unlikely explanations for these differences. Further investigation of the CD cohort may help to explain the reasons for the differences in risk estimates based on internal and external rates.

Acknowledgements

The International Institute of Synthetic Rubber Producers (IISRP) sponsored this research, but the design, conduct, analysis and conclusions are those of the authors. Sponsoring companies were DuPont Dow Elastomers LLC and Enichem Elastomers France. We would like to acknowledge the cooperation and support of the representatives and consultants of IISRP and its member companies, in particular, Sheila Jones, Robin Leonard, Mike Lynch, Stuart Pollard and Paul Poullet. Our special thanks to Dr. Marc Colonna of the Registre du Cancer de l'Isère who coordinated the cohort enumeration and vital status tracing of the Grenoble, France cohort and provided us with a copy of the data file. In addition, we acknowledge the computer programming work of Stephen Sefcik. The research proposal was approved by the Institutional Review Boards (IRB) of the University of Pittsburgh, the University of Oklahoma and the University of Illinois at Chicago. Portions of the data were presented at the 2005 annual meeting of the British Occupational Hygiene Society, April 19, 2005, Manchester, U.K. and the 2005 annual meeting of the American Industrial Hygiene Association, May 25, 2005, Anaheim, CA.

References

[1] J. Lynch, BD monomer and elastomer production processes, Chem.-Biol. Interact. 135/136 (2001) 147–153.
[2] IARC Monographs, Suppl. 7, Vinyl Chloride, Lyon, France, 1987.
[3] IARC Monographs, vol. 71, Chloroprene: Re-evaluation of Some Organic Chemicals, Hydrazine and Hydrogen Peroxide, Lyon, France, 1999.
[4] S. Pell, Mortality of workers exposed to chloroprene, J. Occup. Med. 20 (1978) 21–29.
[5] L. Shouqi, D. Quinan, L. Yuqing, L. Yingfei, Epidemiologic study of cancer mortality among chloroprene workers, Biomed. Environ. Sci. 2 (1989) 141–149.
[6] M. Bulbulyan, A. Margaryan, S. Ilychova, S. Astashevsky, S. Uloyan, V. Cogan, D. Colin, P. Boffetta, D. Zaridze, Cancer incidence and mortality in a cohort of chloroprene workers from Armenia, Int. J. Cancer 81 (1999) 31–33.
[7] M. Colonna, G. Laydevant, A cohort study of workers exposed to chloroprene in the department of Isere, France, Chem.-Biol. Interact. 135/136 (2001) 505–514.
[8] M. Bulbulyan, O. Changuina, D. Zaridze, S. Astashevsky, D. Colin, P. Boffetta, Cancer mortality among Moscow shoe workers exposed to chloroprene, Cancer Causes Contr. 9 (4) (1998) 381–387.
[9] D. Zaridze, M. Bulbulyan, O. Changuina, A. Margaryan, P. Boffetta, Cohort studies of chloroprene-exposed workers in Russia, Chem.-Biol. Interact. 135/136 (2001) 487–503.
[10] J. Rice, P. Boffetta, 1,3-Butadiene, isoprene and chloroprene: reviews by the IARC monographs programme, outstanding issues, and research priorities in epidemiology, Chem.-Biol. Interact. 135/136 (2001) 11–26.
[11] J. Acquavella, R. Leonard, A review of the epidemiology of 1,3-butadiene and chloroprene, Chem.-Biol. Interact. 135/136 (2001) 43–52.
[12] G. Marsh, A. Youk, J. Buchanich, M. Cunningham, N. Esmen, T. Hall, M. Phillips, Mortality patterns among industrial workers exposed to chloroprene and other substances. I. General mortality patterns, Chem.-Biol. Interact., doi:10.1016/j.cbi.2006.08.011, in press.
[13] N. Esmen, K. Kennedy, T. Hall, M. Phillips, Classification of worker exposures, Chem.-Biol. Interact., doi:10.1016/j.cbi.2006.08.008, in press.
[14] N. Esmen, T. Hall, M. Phillips, G. Marsh, Chemical process based reconstruction of exposures for an epidemiological study. I. Theoretical and methodological issues, Chem.-Biol. Interact., doi:10.1016/j.cbi.2006.08.009, in press.
[15] N. Esmen, T. Hall, M. Phillips, E. Jones, H. Basara, G. Marsh, J. Buchanich, Chemical process based reconstruction of exposures for an epidemiological study. II. Estimated exposures to chloroprene and vinyl chloride, Chem.-Biol. Interact., doi:10.1016/j.cbi.2006.08.010, in press.

Please cite this article as: Gary M. Marsh et al., Mortality patterns among industrial workers exposed to chloroprene and other substances, Chemico-Biological Interactions (2006), doi:10.1016/j.cbi.2006.08.012

[16] T. Hall, N. Esmen, E. Jones, H. Basara, M. Phillips, G. Marsh, A. Youk, J. Buchanich, R. Leonard, Chemical process based reconstruction of exposures for an epidemiological study. III. Analysis of industrial hygiene samples, Chem.-Biol. Interact., doi:10.1016/j.cbi.2006.09.004, in press.

[17] A. Youk, G. Marsh, R. Stone, J. Buchanich, T. Smith, Historical cohort study of US man-made vitreous fiber production workers. III. Analysis of exposure-weighted measures of respirable fibers and formaldehyde in the nested case-control study of respiratory system cancer, J. Occup. Environ. Med. 43 (2001) 767–778.

[18] NIOSH The Work-Related Lung Disease Surveillance Report, NIOSH (2002), Publication No. 2003-111; CDC.

[19] G. Marsh, A. Youk, R. Stone, S. Sefcik, C. Alcorn, OCMAP-PLUS, a new program for the comprehensive analysis of occupational cohort data, J. Occup. Environ. Med. 40 (1998) 351–362.

[20] D.R. Cox, Regression models and life tables, J. R. Stat. Soc. 34 (1972) 187–220.

[21] D.R. Cox, Partial likelihood, Biometrika 62 (1975) 269–276.

[22] StataCorp., Stata Statistical Software: Release 8.0, Stata Corporation, College Station, TX, 2004.

[23] Cytel Software: LogXact-5, Software for Exact Conditional Logistic Regression, Cambridge, MA, 2003.

[24] N. Breslow, N. Day, The Design and Analysis of Cohort Studies. Statistical Methods in Cancer Research, vol. II, Oxford University Press, Lyon, 1987.

[25] N. Pearce, H. Checkoway, C. Shy, Time-related factors as potential confounders and effect modifiers in studies based on an occupational cohort, Scand. J. Work Environ. Health 12 (1986) 97–107.

[26] R. Doll, Occupational cancer: a hazard for epidemiologists, Int. J. Epidemiol. 14 (1985) 22–31.

[27] H. Checkoway, N. Pearce, D. Crawford-Brown, Research Methods in Occupational Epidemiology, Oxford University Press, New York, 1989.

[28] A. Blair, P. Stewart, M. O'Berg, W. Gaffey, J. Walrath, J. Ward, R. Bales, S. Kaplan, D. Cubit, Mortality among industrial workers exposed to formaldehyde, J. Natl. Cancer Inst. 76 (1986) 1071–1084.

[29] M. Hauptmann, J. Lubin, P. Stewart, R. Hayes, A. Blair, Mortality from lymphohematopoietic malignancies among workers in formaldehyde industries, J. Natl. Cancer Inst. 95 (2003) 1615–1623.

[30] M. Hauptmann, J. Lubin, P. Stewart, R. Hayes, A. Blair, Mortality from solid cancers among workers in formaldehyde industries, Am. J. Epidemiol. 159 (2004) 1117–1130.

[31] A. Blair, P. Stewart, D. Zaebst, L. Pottern, J. Zey, T. Bloom, B. Miller, E. Ward, J. Lubin, Mortality study of industrial workers exposed to acrylonitrile, Scand. J. Work Health Environ. 24 (suppl 2) (1998) 25–41.

[32] G. Marsh, A. Youk, J. Collins, Reevaluation of lung cancer risk in the acrylonitrile cohort study of the National Cancer Institute and the National Institute for Occupational Safety and Health, Scand. J. Work Health Environ. 27 (2001) 5–13.

[33] G. Marsh, A. Youk, Reevaluation of mortality risks from leukemia in the formaldehyde cohort study of the National Cancer Institute, Regul. Toxicol. Pharm. 40 (2004) 113–124.

[34] G. Marsh, A. Youk, Reevaluation of mortality risks from nasopharyngeal cancer in the formaldehyde cohort study of the National Cancer Institute, Regul. Toxicol. Pharm. 42 (2005) 275–283.

[35] P. Enterline, Pitfalls in epidemiological research, J. Occup. Med. 18 (1976) 150–156.

Please cite this article as: Gary M. Marsh et al., Mortality patterns among industrial workers exposed to chloroprene and other substances, Chemico-Biological Interactions (2006), doi:10.1016/j.cbi.2006.08.012

The Committee on Science, Space, and Technology's Subcommittee on Environment and Subcommittee on Oversight of the U.S. House of Representatives

September 6th Hearing

Examining the Scientific and Operational Integrity of EPA's Iris Program

THE IRIS REVIEW PROCESS: CHLOROPRENE AND THE CRITICALITY OF GOOD SCIENCE

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RAMBOLL ENVIRON

The IRIS Review Process: Chloroprene and the criticality of good science

Overview

The US Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS) compiles and evaluates available scientific studies to determine the potential for chemicals to cause human health effects, and to conduct risk assessments that indicate the exposure levels at which risk of health effects is increased. These evaluations are relied upon by federal, state, local as well as international regulatory and public health agencies. Therefore, the validity of the IRIS evaluations is paramount. Over the last decade the methods used in and ultimate quality of IRIS reviews have been criticized by numerous entities, most notably, by expert panels of the National Academy of Sciences (NRC 2011, 2014).

EPA's 2010 IRIS Toxicological Review of Chloroprene (Final Report) (hereafter, "the 2010 Review")[1] serves as one example where several of the more recent concerns expressed by two National Research Council (NRC) Committees of the National Academy of Sciences (NAS) can impact the quality of the scientific evaluation and lead to the derivation and publication of official risk numbers (intended to quantify the relationship between chloroprene exposure and the risk of human cancers), which in the case of chloroprene are not scientifically valid. For example, the Inhalation Unit Risk (IUR) that EPA published for chloroprene appears to be *156 times* greater than a more scientifically accurately derived value. Furthermore, EPA's extreme IUR for chloroprene – a chemical EPA did not even classify as a "known" human carcinogen due to uncertainty - is orders of magnitude higher than the IURs for other chemicals for which the integration of evidence demonstrates carcinogenicity in humans (such as benzene and vinyl chloride) and are classified as "known" human carcinogens. Clearly, EPA's IUR for chloroprene needs to be corrected.

Based on a detailed critical evaluation of the 2010 Review conducted by Ramboll Environ US Corporation (Ramboll Environ), and sponsored by Denka Performance Elastomer LLC ("DPE"), several scientific errors and other problems were identified that likely gave rise to the extreme IUR value that EPA derived. The most important of these scientific issues include the following:

- The 2010 Review failed to critically evaluate the quality of each of the published epidemiological studies on workers highly exposed to chloroprene and apparently gave equal weight to all studies regardless of quality. Workers' exposure to chloroprene is expected to be thousands of times higher than that of the general public. Suggestive associations are reported among the weakest studies (including studies from Armenia, Russia and China); in contrast, the stronger studies (primarily from the US and UK) do not demonstrate increased cancer risks. EPA noted: "In humans, significant increases in liver cancer

[1] U.S. EPA. IRIS Toxicological Review of Chloroprene (Final Report). U.S. Environmental Protection Agency, Washington, DC, EPA/635/R-09/010F, 2010.

mortality were observed in four occupational epidemiology studies (out of nine total studies)." The four studies did not include the highest quality study.

- The 2010 Review ignored the conclusion of the highest quality and most informative epidemiological study published to date: "We conclude that persons exposed to chloroprene or vinyl chloride at the levels encountered in the four study sites did not have elevated risks of mortality from any of the causes of death examined, including all cancers combined and lung and liver cancer, the cancer sites of *a priori* interest" (Marsh et al., 2007a, 2007b). Rather, the 2010 Review highlighted out of context statistical results based on small subgroups of workers, even though none of the risk estimates was statistically significant (i.e., likely arose due to chance). EPA noted: "Relative risk estimates for liver cancer (while not statistically significant) increased with increasing exposure, indicating a dose-response trend." However, even the reported "trend" was not statistically significant (p=0.09).
- The 2010 Review failed to properly account for large and well-recognized differences between mice and humans in deriving the IUR. The National Toxicology Program (NTP) conducted a study in which male and female mice of a specific strain, as well as male and female rats, were exposed to high concentrations of chloroprene. More tumors were observed in the exposed mice than the unexposed mice, and more in mice compared to rats, with the mouse data then used as the main data for estimating potential cancer risk to humans. However, scientific evidence providing significant and well-documented physiological and metabolic differences between mice and humans were not fully considered. Furthermore, the effects driving the estimates of cancer risk (lung cancer observed in female mice) were not elevated with chloroprene exposure in experiments using rats or hamsters, suggesting that mice are not equivalent to humans and far more sensitive to chloroprene than other animals or humans.

Ramboll Environ, using published data and standard EPA risk assessment methods that properly account for these large differences between female mice and humans (and that EPA has used in IUR calculations for other chemicals), derived a corrected IUR, demonstrating that the EPA IUR was overestimated 156-fold. Other quantitative evaluations in the 2010 Review (e.g., Reference Concentration) also are likely to be incorrect if the interspecies differences are not fully appreciated.

As emphasized in reviews by prominent scientific committees, most notably those of the NAS (NRC 2011, 2014), significant improvements to the IRIS review methods and process are needed, including greater transparency. Additionally, fuller engagement of scientists most knowledgeable about the chemicals under review – including those potentially funded by industry – would contribute to scientific quality and help identify and correct scientific errors before reviews are finalized.

Regardless of future improvements, some IRIS Reviews that are in progress (e.g., formaldehyde) or have been finalized (e.g., chloroprene) need to be validated, with mechanisms for correcting past errors. Regulations and other decisions based on the erroneous IUR for chloroprene, for example, will not be based on sound science, and likely will have serious impacts. Scientifically, the magnitude of this difference

between the published and recalculated IUR is very large, and clearly warrants re-evaluation and correction.

Impetus for Ramboll Environ's evaluation of the 2010 Review

In December 2015, EPA finalized and published the 2011 National Air Toxics Assessment (NATA), which indicated an extremely high off-site air pollution cancer risk from emissions of chloroprene from what is now DPE's Neoprene production facility in LaPlace, Louisiana. The NATA was derived based on the IUR from the 2010 Review and the emission profile of the Neoprene facility. The NATA findings precipitated adverse public opinion, enforcement actions, and a class action lawsuit, all of which potentially have serious economic implications for DPE and the community.

Immediately after the release of the NATA cancer risk conclusions, DPE asked Ramboll Environ to conduct an independent evaluation of the 2010 Review, including a critical review and synthesis of all relevant published epidemiological and toxicological literature, with a focus on validating EPA's cancer IUR as reported in the 2010 Review. DPE recognized Ramboll Environ's scientific work and interaction with the IRIS program regarding the IRIS Draft Formaldehyde Toxicological Review, which was the focus of the NRC 2011 peer review and their criticisms of the IRIS process and methods.

Highlights of the Ramboll Environ evaluation as of one year ago were presented to EPA on August 9, 2016 at an event EPA entitled, "IRIS Assessment of Chloroprene," and attended by 13 EPA representatives – including the Acting Director of EPA's National Center for Environmental Assessment (NCEA) and the Director of IRIS – plus three representatives of the Louisiana Department of Environmental Quality. Ramboll Environ's presentation to the group can be found at the following link: https://cfpub.epa.gov/ncea/iris2/events.cfm. A follow-up letter to Dr. Vandenberg is included as an Attachment. This letter highlights some of the difficulties encountered in seeking a correction of the 2010 Review.

Subsequently, the full Ramboll Environ report was submitted to EPA as part of a request for correction, and is available at the following link: https://www.epa.gov/quality/rfc-17002. This report lays out the exact approach used in calculating an IUR for chloroprene using the best scientific methods used by EPA in other chemical evaluations, and considering the quality of the epidemiological and toxicological evidence used in evaluating chloroprene's carcinogenicity and risk numbers.

Ramboll Environ's evaluation of the 2010 Review

In the 2010 Review, EPA classified chloroprene as "likely to be carcinogenic to humans" and not the more definitive "known to be a human carcinogen," primarily based on EPA's recognition that the evidence was insufficient to classify it as a known human carcinogen. However, even classifying chloroprene as "likely to be carcinogenic to humans" was subject to and influenced by questionable interpretations of the published epidemiological and toxicological evidence.

Nevertheless, EPA proceeded to derive an IUR for chloroprene that is the 5th highest IUR (not including carcinogenic metals or coke oven emissions) EPA ever has developed, even among chemicals EPA or the World Health Organization's (WHO's) International Agency for Research on Cancer (IARC) classifies as "known" or likely/probable human carcinogens. Specifically, the IUR for lifetime exposure to chloroprene derived by EPA is 5×10^{-4} per microgram per cubic meter ($\mu g/m^3$).

The chloroprene IUR is sufficiently large that EPA should have realized prior to publishing the 2010 Review that the value was anomalous. Despite the fact that the 2010 Review underwent several peer-reviews, the large and obvious discrepancy between EPA's IUR for chloroprene and other IURs derived by EPA appears to have gone further unnoticed or unreported. The reasons for this are not clear, but call into question the quality of the peer-review process that IRIS has relied upon to draw conclusions regarding the potential for cancer risk in humans.

The main objective for the Ramboll Environ scientific evaluation of the 2010 Review was to evaluate the IUR for chloroprene as derived by EPA, and to provide improved and transparent scientific methods, interpretations and risk calculations to facilitate scientifically justified corrections for EPA's consideration.

The main elements of the Ramboll Environ assessment are presented below in four sections: Epidemiological Evidence; Toxicological Evidence; Chloroprene Carcinogenicity Classification; and, Deriving the Chloroprene IUR.

Epidemiological Evidence

A critical piece to understanding the potential cancer effects in humans from exposure to chloroprene is a rigorous evaluation of the occupational epidemiological literature. Workers involved in producing and directly using chloroprene are likely the most highly exposed individuals, and the occupational setting facilitates epidemiological methods for enumerating cohorts of workers, estimating levels of exposure and following workers over time to observe the rates at which various outcomes, including cancers, occur. The epidemiological evidence relevant to chloroprene carcinogenicity and that EPA correctly identified includes findings from occupational cohorts from the US, France, Ireland, Armenia, Russia and China. However, the 2010 Review of the epidemiological literature was methodologically irregular, particularly with respect to how individual study quality was assessed and weighted in the overall weight-of-evidence assessment. In fact, it is not clear whether EPA critically evaluated the quality of each of the published epidemiological studies on workers highly exposed to chloroprene and their respective cancer risks, and if so, the methods and rationale for how this was done were not transparent. For example, where suggestive positive associations are seen is among the weakest studies (including studies from Armenia, Russia and China); in contrast, the stronger studies (primarily from the US and UK) do not demonstrate increased cancer risks. The NRC recommendations regarding the IRIS review process (2011, 2014) underscore the importance of considering the quality of individual studies, giving greater weight to high-quality studies in the weight-of-evidence evaluation, and providing transparency in applying and documenting these methods.

A critical review of the same literature cited in the 2010 Review had already been published by Bukowski, as of 2009. The Table below is adapted from a similar table in that publication:

Table: Quality Rankings for Cohort Studies of Cancer Risks from Occupational Chloroprene Exposure

EPA Criteria	Marsh et al. (2007 a,b) Study				Other Studies			
	Kentucky[1]	North Ireland[1]	Louisiana[1]	France-Mort*[1]	Armenia[2]	France-Incid**[3]	Russia[4]	China[5]
Clear objectives	H‡	H	H	H	H	H-M	H	M
Comparison groups	H	H-M	H-M	M	M	M	M-L	L
Exposure	H	H	H	H	M	M	L	L
Follow-up	H	H-M	H	H-M	M-L	M-L	M-L	M-L
Case ascertainment	H	H-M	H-M	H-M	M	M	M	H-M
Control of bias	H-M	H-M	H-M	M	M-L	M	M	M-L
Sample size	H	H	M	L	M-L	L	H-M	M-L
Data collection and evaluation	H	H	H	H	M	M	M-L	M-L
Adequate response	H	H	H	H	M	M	M	H-M
Documentation of results	H	H	H	H	M-L	M	M	L
Overall rank (1=best)	**1**	**2**	**3**	**4**	**5**	**5**	**5**	**6**

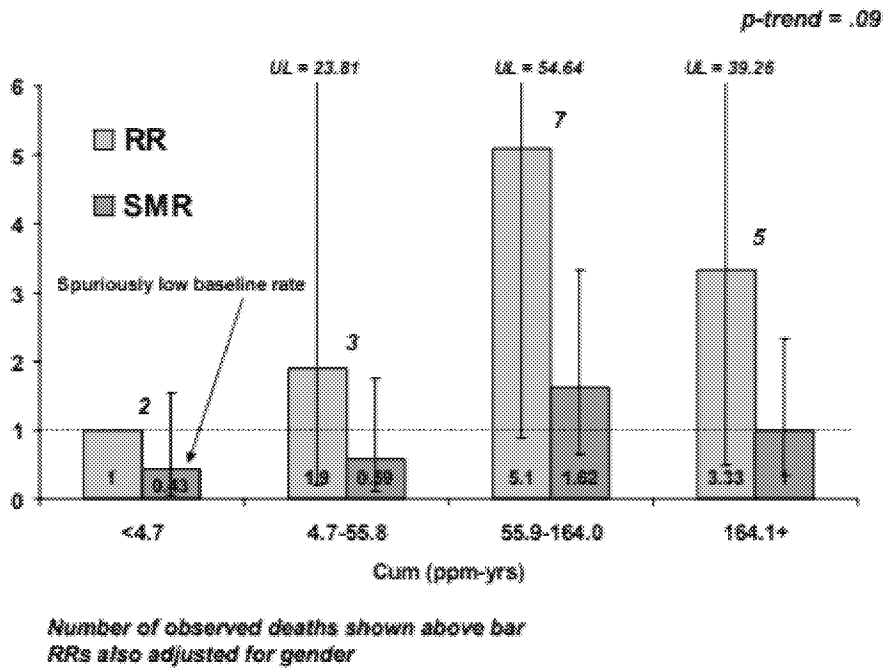
Source: Bukowski 2009 * Mort=Mortality ** Incid=Incidence ‡ Subjective estimate of study quality for each specific criterion H=high, M=medium, L=low; 1 – Marsh et al. 2007; 2 – Bulbulyan et al. 1999; 3 – Colonna and Laydevant 2001; 4 – Bulbulyan et al. 1998; 5 – Li et al. 1989

From this evaluation of individual study quality, it is clear that the first four studies received predominately "high" or "high-medium" ratings, in contrast with the final four studies that received predominately "medium" or lower ratings (Bukowski 2009). The Marsh et al. study (2007a, 2007b) combined the data from these four high-quality studies, and represent the most methodologically rigorous epidemiological evidence available to date. This study has the largest overall cohort size and the most rigorous follow-up, providing the greatest statistical power to detect an increased cancer risk should one exist. In contrast with the low-quality studies, the Marsh et al. study (2007a, 2007b) has the most comprehensive exposure assessment, including assessment and consideration of exposure to other occupational carcinogens (i.e., potentially confounding agents) such as vinyl chloride.

Importantly, the Marsh et al. (2007a, 2007b) study reported no excess occurrence of lung or liver cancers among chloroprene exposed workers when compared to the general population reference group. For all exposed workers at all plants combined, observed liver cancer mortality was 72% of what would be expected based on rates in the unexposed general population (this is expressed by the standardized mortality ratio, or SMR). The comparable finding for all exposed workers in the largest plant

(Louisville) was 90% of expected. Both these values demonstrate no increased risk for liver cancer. By exposure sub-group, none of the SMRs was statistically significantly elevated, and three of the four were below 1.0 (the value when observed and expected are equal). Furthermore, there was no statistically significant trend of increasing risk with increasing exposure (see Figure).

Figure



Source: Figure from comments submitted by Andrea V. Malinowski to EPA, Docket ID No. EPA-HQ-ORD-2009-0217, based on data from Marsh et al. 2007b

For lung cancers – the cancer site that provided the highest incidence in the mouse and was hypothesized to be relevant to chloroprene exposure – the Marsh et al. study (2007a, 2007b) documented a statistically significant 25% *deficit* of lung cancer mortality for all plants combined. Specifically, the pooled study data observed 112 fewer lung cancer deaths than would be expected based on unexposed population rates. Findings for each of the four individual plants were consistent (i.e., suggesting a deficit) although only one – Louisville, the largest plant – had a statistically significant deficit (89 fewer lung cancer deaths observed than expected). In contrast, EPA noted in the IRIS review that several studies reported higher SMRs for lung cancer among workers exposed to chloroprene, although few of the associations were significant and none of the studies controlled for confounding by smoking status, a strong indicator of lung cancer.

Nevertheless, EPA appears to have given no more weight to the most recent and rigorous epidemiological evidence (Marsh et al., 2007a, 2007b) showing no increased occurrence of liver and lung cancer than to the poorer quality Russian, Armenian, and Chinese studies, all of which had significant limitations. These limitations had been identified by others than Bukowski (2009). Rice and Boffetta (2001) conducted a review that included cohorts from the US (Pell 1978), China (Li et al. 1989), Russia (Bulbulyan et al. 1998) and Armenia (Bulbulyan et al. 1999) and noted significant methodological limitations in these studies, including unclear documentation for cohort enumeration, inadequate reference rates for standardized ratios, a lack of detailed histopathology of liver cancer cases, and limited or no information on potential co-exposures. They also remarked that the occupational chloroprene exposure assessment was poor for all published studies at that time, and the statistical power of the available studies was low due to the small number of observed cancers of interest.

In addition to discounting the Marsh et al. (2007a, 2007b) study findings relative to the weaker evidence, EPA also appears to have misinterpreted the Marsh et al. (2007b) results. Specifically, the 2010 Review interpreted a statistical correlation between exposure level and liver cancer risk relative to a comparison subgroup where the comparison group exhibited anomalously fewer cancers than expected, creating the appearance of an increased risk in the higher exposure groups (see Figure). Specifically, note that the 2 observed liver cancer deaths represent less than half the expected number. In turn, using this as the referent or comparison group effectively inflates the other categories by a factor of 2.3. Furthermore, that there were only two liver cancer deaths in this category contributed to large instability in all categories due to chance alone, i.e., the impact of one fewer or one more liver cancer death in this category would spuriously generate conflicting results.

The issues summarized here suggest that EPA's 2010 Review relied on incomplete evaluation and misinterpretation of the published epidemiological evidence. Properly evaluated, interpreted and weighted, the weight of epidemiological evidence does not demonstrate an association between occupational chloroprene exposure and increased incidence of liver or lung cancer.

Separate from the evaluation of the 2010 Review, Ramboll Environ examined cancer incidence data from the Louisiana Tumor Registry, comparing rates for St. John the Baptist Parish where the DPE Neoprene plant is located, with those of the state of Louisiana. For all cancers combined, the rate in the five most recent years in St. John the Baptist Parish was 463.2, compared with 478.7 for the state of Louisiana, that is, cancer rates in St. John the Baptist Parish were about 3% below the state average. For lung cancers, the rate in St. John the Baptist Parish was 60.1 compared with 70.5 for the state of Louisiana, that is, lung cancer rates in St. John the Baptist Parish are 14.7% lower than the state average. Too few liver cancers have occurred in St. John the Baptist Parish to be publically reported.[2] Though these official data are at best an indirect indicator of a population impact of the DPE facility operations, they do not provide evidence that the parish in which the DPE facility operates has elevated cancer rates.

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[2] https://statecancerprofiles.cancer.gov/incidencerates/index.php?stateFIPS=22&cancer=001&race=00&sex=0&age=001&type=incd&sortVariableName=rate&sortOrder=default#results.

Toxicological Evidence

As with the epidemiological studies, the toxicological evidence also should be evaluated in ways that adhere to EPA's own standard risk evaluation methodologies and conform to the NRC recommendations. The 2010 Review relied on the animal toxicological data as basis for deriving the chloroprene IUR, and specifically, the animal studies conducted by the National Toxicology Program (NTP 1998). Overall, this study, which included both mice and rats, demonstrated very little consistency across species in tumor incidence and tumor locations, but also demonstrated a unique sensitivity in a particular strain of female mice in which lung tumors appeared to be the most sensitive endpoint. Findings were specific to mice and not generalizable across the other animal species tested, including rats and hamsters. Given the striking differences in response in mice compared to other laboratory species, it is critically important to identify and evaluate possible differences in pharmacokinetics between animal species and to consider differences between mice and humans. The impact of this on the IUR is substantial, as discussed below.

In addition to revisiting the reliance on the animal dataset for the estimation of the IUR, a more rigorous re-evaluation and integration of the cytotoxic and genotoxic evidence for chloroprene is needed, consistent with NRC (2011, 2014) recommendations. The Ramboll Environ evaluation of the published toxicological literature found that the evidence from these studies indicates that chloroprene acts through a different mode of action (MOA) than 1,3-butadiene, a structurally similar known human carcinogen, but used for comparison and to draw conclusions by EPA in the 2010 Review. Using the NRC (2011, 2014) recommendations as guidelines, review of chloroprene's genotoxicity profile appears to lack several attributes necessary to conclude that there is a mutagenic MOA. Instead, the evidence supports site-specific cytotoxicity as a more likely MOA. This contradicts EPA's conclusion that chloroprene acts *via* a mutagenic MOA, and alone inflated EPA's IUR by about 60%.

Chloroprene Carcinogenicity Classification

The 2010 Review determined that chloroprene was "likely to be carcinogenic to humans" based on EPA's conclusions of (1) statistically significant and dose-related information from the NTP (1998) chronic inhalation bioassay data demonstrating the early appearance of tumors, development of malignant tumors, and the occurrence of multiple tumors within and across animal species; (2) evidence of an association between liver cancer risk and occupational exposure to chloroprene; (3) suggestive evidence of an association between lung cancer risk and occupational exposure; (4) a proposed mutagenic mode of action (MOA); and (5) structural similarities between chloroprene and known human carcinogens, 1,3-butadiene and vinyl chloride. As has been demonstrated in this report, three of the five EPA conclusions are not supported by the weight of evidence, and the fourth—structural similarities—has been shown not to be informative, as the evidence available for the chemicals demonstrates different modes of action.

The Ramboll Environ evaluation of the 2010 Review demonstrated considerable misinterpretation of the available science to support the "likely to be carcinogenic to humans" classification. For example, the epidemiological evidence, based on an appropriate weight-of-evidence approach, fails to demonstrate clearly increased risks among exposed occupational groups and the general population, and a weak difference between exposed and unexposed workers reflecting a deficit among the least exposed. The claim that chloroprene is mutagenic is not supported by the overall evidence. Although there are structural similarities between chloroprene and 1,3-butadiene or vinyl chloride, the toxicological evidence that supports possible modes of action demonstrates substantial differences between chloroprene, vinyl chloride, and 1,3-butadiene. Little discussion of critical uncertainties in relying on the mouse data from NTP (1998) to predict the potential for carcinogenic risk in humans is offered in the 2010 Review, given ample evidence of important pharmacokinetic differences between mice and other species.

The weight-of-evidence evaluation supports a reclassification. Based on the limited evidence remaining to support the potential carcinogenicity of chloroprene, a more appropriate classification of chloroprene would be "suggestive evidence of carcinogenic potential." In any case, a clearer weight-of-evidence narrative is needed that addresses the current uncertainties.

Deriving the Chloroprene IUR

In the 2010 Review, EPA derived the current chloroprene IUR based on a number of assumptions that are not substantiated by the scientific evidence, contributing to overestimation of an already conservative risk estimate (i.e., one based on the most sensitive species, gender, and endpoint). Specifically, EPA based the chloroprene IUR on a composite estimate of risk based on multiple tumors observed primarily in mice, instead of relying on just the most sensitive endpoints in mice (lung tumors) which is consistent with standard EPA methods. EPA then assumed that the female mouse-based IUR was representative of continuous human exposure, and that lung tumors were a result of systemic rather than portal-of-entry effects; EPA also rounded up calculations at various stages of adjustment, and these were compounded. Finally, EPA applied an age-dependent adjustment factor (ADAF) based on insufficient data to support a claimed mutagenic MOA. All of these assumptions are not supported by the scientific evidence and contributed to unrealistic increases in the final IUR, as presented in the Ramboll Environ report submitted to EPA as part of DPE's Request for Correction.

The most important correction of the IUR is that it should seek to be predictive of human response. At the time of the 2010 Review, Himmelstein et al. (2004a, 2004b) had published a paper that described a physiologically based pharmacokinetic (PBPK) model for chloroprene. The model provided a means to adjust the exposures associated with tumors in the mouse to corresponding human exposures, and the model integrates the available data that explain why the mouse is the most sensitive species and why humans would be comparatively much less sensitive to the effects of chloroprene exposure. The hypothesis that differences in pharmacokinetics are determinants of the observed species differences has been demonstrated for other chemicals reviewed by EPA, including vinyl chloride. In the 2010 Review, EPA

acknowledged that its results would be improved with the use of a PBPK model, but that all of the required data were not available. However, all of the quantitative data necessary to refine and verify the critical metabolic parameters for the existing peer-reviewed PBPK model for chloroprene were published prior to the publication of the 2010 Review. Since then, additional data have been published, and these newer findings further validate the model and its use in demonstrating consistency with the epidemiological evidence, and its use in deriving the chloroprene IUR (Thomas et al. 2013, Yang et al. 2012, Allen et al. 2014). In particular, Allen et al. (2014) derived an IUR based on consideration of pharmacokinetic differences between mice and humans and estimated an IUR that was 100 times lower than EPA's value, using a method which integrates both the animal and human evidence. Importantly, consideration of the IUR reported by Allen et al. (2014) in comparison with IURs for known human carcinogens, such as vinyl chloride and 1,3-butadiene, is consistent with the stronger and more consistent epidemiological evidence of human carcinogenicity for these compounds compared to chloroprene.

Ramboll Environ performed an updated analysis by applying the peer-reviewed published results from validated PBPK models (Yang et al. 2012) to arrive at an IUR that accounts for the known interspecies differences in pharmacokinetics. Standard EPA methodology and conservative assumptions were applied to estimate the potential cancer risks for chloroprene. The revised IUR is $1.1x\ 10^{-2}$ per ppm or 3.2×10^{-6} per $\mu g/m^3$, which is of the same order of magnitude as the IUR derived by Allen et al. (2014), and which better reflects the scientific understanding of potential chloroprene cancer effects in humans. In contrast, the EPA derived an IUR for lifetime exposure to chloroprene of 5×10^{-4} per microgram per cubic meter ($\mu g/m^3$), a value approximately 156 times higher than what Ramboll Environ considers the best estimate using standard EPA methods and available data. The revised value also is consistent with the results from validated PBPK models and comparisons with other structurally relevant compounds, such as vinyl chloride and 1,3-butadiene, that are recognized as known human carcinogens.

There is little scientific support for each of EPA's conservative assumptions and subsequent adjustments. Combining a fuller understanding of interspecies pharmacokinetic differences and validated PBPK models with the results from the strongest epidemiological data provides the scientific grounds for correcting the 2010 IUR and calls into question the strength of the evidence to support a "likely to be carcinogenic to humans" classification. Similar adjustments should also be considered in estimating the chloroprene inhalation reference concentrations (RfC), as species- and strain-specific differences are noted. This will assure that policies and decisions resting on these toxicity values meet the test of sound science, transparent methods, and reproducible findings.

Conclusions

EPA's 2010 Review of chloroprene offers examples of several broader issues with the quality of IRIS Reviews including those of the NAS (NRC 2011, 2014), including evaluation of individual toxicological and epidemiological studies for quality, and transparency in weight-of-evidence integration to validly determine a chemical's potential carcinogenicity and derive accurate risk numbers. For chloroprene, the IUR

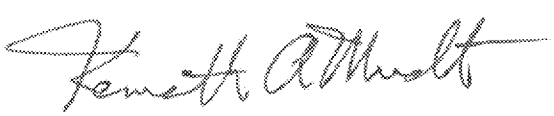
that EPA derived in the 2010 Review appears to be at least 100-fold inflated, and, based on a best-methods approach performed and documented by Ramboll Environ, over-estimated by as much as 156-fold. Risk assessments based on this IUR, such as the National Air Toxics Assessment, incorporate the overestimated value leading to grossly exaggerated human cancer risk predictions. This undoubtedly and unnecessarily triggers regulatory and legal action, as well as incites fear in the workers exposed to chloroprene, as well as those in the surrounding communities who may be exposed at much lower concentrations.

As outlined above, the overestimation of the IUR is the product of several scientific shortfalls or errors, including misreading of the epidemiological evidence, the likely erroneous assumption that chloroprene is mutagenic, an under-appreciation and subsequent incomplete consideration of the large pharmacokinetic differences between the female mice and humans, as well as other issues.

Scientifically, updating the IRIS Review of chloroprene is warranted, possibly including reconsideration of the carcinogenicity classification in light of a more accurate interpretation of the epidemiological evidence. However, and more urgently, a correction to the IUR is needed, based on the Ramboll Environ analysis provided to EPA in DPE's recent Request for Correction. The IUR published in the 2010 Review requires correction to address flaws that are consistent with the critique of the IRIS program by NRC. Specifically, an updated IUR should be based on the best available methodology as well as a valid, transparent, and systematic interpretation of the body of published evidence. Although there are variations in how IURs are derived, proper application of established EPA risk assessment methods – including the PBPK model to account for extreme interspecies differences – should generate an IUR that is 100-150+ times lower than that published in the 2010 Review. The methods presented in the Ramboll Environ report could serve as a starting point, reducing the time and resources EPA otherwise would expend.

Correction additionally is critical given that the IUR published in the 2010 Review is being used by EPA to support enforcement actions and underlies a class action lawsuit. The chloroprene example highlights deficiencies in the IRIS process that need to be addressed as soon as possible.

Respectfully submitted,



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References

Allen BC, Van Landingham C, Yang Y, Youk AO, Marsh GM, Esmen N, Gentry PR, Clewell III HJ, and Himmelstein MW. (2014). A constrained maximum likelihood approach to evaluate the impact of dose metric on cancer risk assessment: Application to b-chloroprene. *Regulatory Toxicology and Pharmacology* 70: 203–213.

Bukowski JA. (2009). Epidemiologic evidence for chloroprene carcinogenicity: Review of study quality and its application to risk assessment. *Risk Analysis* 29(9):1203–1216.

Bulbulyan MA, Margaryan AG, Ilychova SA, Astashevsky SV, Uloyan SM, Cogan VY, Colin D, Boffetta P, and Zaridze DG. (1999). Cancer incidence and mortality in a cohort of chloroprene workers from Armenia. *International Journal of Cancer* 81(1):31–33.

Bulbulyan MA, Changuina OV, Zaridze DG, Astashevsky SV, Colin D, and Boffetta P. (1998). Cancer mortality among Moscow shoe workers exposed to chloroprene (Russia). *Cancer Causes and Control* 9(4):381–387.

Colonna M and Laydevant G. (2001). A cohort study of workers exposed to chloroprene in the department of Isère, France. *Chemico-Biological Interactions* 135-136:505–514.

Himmelstein MW, Carpenter SC, and Hinderliter PM. (2004a). Kinetic modeling of betachloroprene metabolism: I. In vitro rates in liver and lung tissue fractions from mice, rats, hamsters, and humans. *Toxicological Sciences* 79(1):18–27.

Himmelstein MW, Carpenter SC, Evans MV, Hinderliter PM, and Kenyon EM. (2004b). Kinetic modeling of beta-chloroprene metabolism: II. The application of physiologically based modeling for cancer dose response analysis. *Toxicological Sciences* 79(1):28-37.

Li SQ, Dong QN, Liu YQ, and Liu YG. (1989). Epidemiologic study of cancer mortality among chloroprene workers. *Biomedical and Environmental Sciences* 2(2):141–149.

Marsh GM, Youk AO, Buchanich JM, Cunningham M, Esmen NA, Hall TA, and Phillips ML. (2007a). Mortality patterns among industrial workers exposed to chloroprene and other substances: I. General mortality patterns. *Chemico-Biological Interactions* 166(1-3):285–300.

Marsh GM, Youk AO, Buchanich JM, Cunningham M, Esmen NA, Hall TA, and Phillips ML. (2007b). Mortality patterns among industrial workers exposed to chloroprene and other substances: II. Mortality in relation to exposure. *Chemico-Biological Interactions* 166(1-3):301–316.

NRC (National Research Council). (2014). Review of US EPA's Integrated Risk Information System (IRIS) Process. Washington, DC. National Academies Press.

NRC (National Research Council). (2011). Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. Washington, DC: National Academies Press.

NTP (National Toxicology Program). (1998). Toxicology and carcinogenesis studies of chloroprene (CAS No. 126-99-8) in F344 rats and B6C3F1 mice (inhalation studies). Public Health Service, U.S. Department of Health and Human Services; NTP TR-467. http://ntp.niehs.nih.gov/ntp/htdocs/LT)rpts/tr467.pdf.

Pell S. (1978). Mortality of workers exposed to chloroprene, *Journal of Occupational Medicine* 20:21–29.

Rice JM and Boffetta P. (2001). 1,3-butadiene, isoprene, and chloroprene: Reviews by the IARC monographs programme, outstanding issues, and research priorities in epidemiology. *Chemico-Biological Interactions* 135-136:11–26.

Thomas RS, Himmelstein, MW, and Clewell HJ III, Yang Y, Healy E, Black MB, and Andersen ME. (2013). Cross-species transcriptomic analysis of mouse and rat lung exposed to chloroprene. *Toxicological Sciences* 131(2): 629–640. doi:10.1093/toxsci/kfs314

U.S. EPA. IRIS Toxicological Review of Chloroprene (Final Report) (2010). U.S. Environmental Protection Agency, Washington, DC, EPA/635/R-09/010F, 2010.

U.S. EPA. 2011 National Air Toxics Assessment (2015). U.S. Environmental Protection Agency, Washington, DC. https://www.epa.gov/national-air-toxics-assessment/2011-national-air-toxics-assessment

Yang Y, Himmelstein MW, and Clewell HJ. (2012). Kinetic modeling of b-chloroprene metabolism: Probabilistic in vitro–in vivo extrapolation of metabolism in the lung, liver and kidneys of mice, rats and humans. *Toxicology in Vitro* 26:1047–1055.

Attachment

RAMBOLL ENVIRON

ENVIRONMENT
& HEALTH

John Vandenberg, PhD
Director of Research at NCEA
109 T.W. Alexander Drive
Research Triangle Park, NC 27709

Sent via e-mail

RE: FOLLOW-UP TO THE MEETING AT RTP

Dear Dr. Vandenberg,

August 23, 2016

Ramboll Environ
28 Amity Street
Suite 2A
Amherst, MA 01002
USA

T +1 413 8354350
www.ramboll-environ.com

Thank you for setting up and orchestrating the "listening session" on Tuesday August 9th, 2016 at your offices. Dr. Gentry and I appreciate the opportunity to present the findings from our independent review of chloroprene's potential carcinogenicity, based on all available data and state-of-the-art methods for critically reviewing and synthesizing epidemiology, toxicology and mechanistic studies, and for integrating evidence across these lines of inquiry.

As discussed after our presentation of the science, we acknowledge and appreciate your explanation of the IRIS Program's resource constraints, the complex procedures in place for selecting substances for IRIS review or re-review, as well as what you described as the "full docket" of current and future IRIS reviews. Based on this feedback, we understand that the IRIS Program will not at this time undertake a new review of chloroprene – or consider any revisions to the risk numbers – primarily due to resource constraints.

This, as you can understand, leaves our client, Denka Performance Elastomer, LLC (DPE), in a very difficult position, and unjustifiably so from a scientific standpoint. During our meeting, we outlined important new information demonstrating that an IRIS chloroprene IUR derived today would be vastly different and more compatible with other IURs for other chemicals. As we demonstrated during our meeting, properly employing validated PBPK models leads to an IUR for chloroprene that is more than 100-fold lower than the 2010 IRIS value. In fact, the 2010 IRIS Review of Chloroprene astutely acknowledged this very flaw: "Ideally, a PBPK model for the internal dose(s) of the reactive metabolite(s) would decrease some of the quantitative uncertainty in interspecies extrapolation; however, current PBPK models are inadequate for this purpose" (US EPA, 2010, Section 3)[1]. The information and methods required for chloroprene now have been peer-reviewed, published, and validated, with similar models and methods applied by EPA in comparable risk evaluations (such as vinyl chloride).

[1] US EPA 2010. Toxicological Review of Chloroprene. In support of Summary Information on the Integrated Risk Information System. Washington, DC: U.S. Environmental Protection Agency.

We also noted what we consider a misinterpretation of the body of epidemiological evidence, largely due to discounting the negative results published from the 2007 Marsh et al. study, which is also the strongest epidemiological study, in favor of results from much weaker studies. The integration of the entirety of epidemiological evidence supports the updated toxicology and mechanistic evidence indicating important and substantial differences between humans and mice, specifically in terms of metabolism, which are directly related to estimating the potential cancer risks for chloroprene. This no longer can be ignored. Taking the most up-to-date information into consideration in the context of using science to inform EPA policy and regulation is entirely consistent with the Agency's very public "mission statement" to ensure that "national efforts to reduce environmental risk are based on the best available scientific information." [2]

Without a commitment on the Agency's part to reexamine the 2010 IRIS assessment's IUR derivation in light of the new information, EPA and the Louisiana Department of Environmental Quality have advised DPE that it will be required to meet extremely stringent emissions limits, which may not be attainable, and that are not based on the best available science. We also have seen that the IUR is being used to inform important regulatory and other federal and state government actions, as well as public statements with respect to the possible cancer risks to people who live and work in the community in which our client's facility is located.

Notwithstanding the IRIS Program's resource constraints, we genuinely look forward to any thoughts or ideas you or Dr. Cogliano might have with respect to how we might work collaboratively with you and the program office within EPA that is relying on the 2010 IRIS Assessment, to timely improve and update the IUR. The IUR for chloroprene (as well as actions that are derivative of that IUR) should be more in line with those of other substances, such as vinyl chloride, that provide stronger evidence than chloroprene of carcinogenicity in humans.

We, too, will be exploring various available avenues, and will keep you informed. One possibility would be for us to file a request for correction (RFC). Our ultimate goal, as I initially mentioned to Dr. Cogliano when I first approached him, is to improve the risk calculation based on currently available science and evidence-based processes, which have evolved since the completion of the 2010 Chloroprene Toxicological Review, and to do so in a way that creates the lowest demands on already limited resources. Thank you again, and I look forward to continuing our discussion.

Yours sincerely

Kenneth A. Mundt, PhD, FACE
Health Sciences Practice Network Leader
D +1 413 835 4360
M +1 413 885 1345
kmundt@ramboll.com

cc: Dr. Vincent Cogliano

[2] https://www.epa.gov/aboutepa/our-mission-and-what-we-do

Cancer Incidence in St. John the Baptist Parish, 2004-2013

	Incidence Rates*			Incidence Counts, Ten Years	
	U.S. **	Louisiana	St. John	Louisiana	St. John
All cancers	458.9	485.6	474.7	216,439	1,953
Oral cavity & pharynx	10.9	12.6	13.4	5,757	59
Esophagus	4.4	5.0	5.2	2,281	22
Stomach	7.5	7.9	11.3	3,474	45
Colorectum	44.2	51.0	51.7	22,631	211
Liver	7.9	7.8	7.5	3,601	31
Pancreas	12.3	13.5	16.2	5,937	59
Larynx	3.3	5.4	4.5	2,489	20
Lung and Bronchus	60.3	74.7	63.6	33,190	254
Melanoma of the Skin	21.4	14.9	9.0	6,500	37
Breast	67.2	66.1	66.8	29,395	289
Cervix Uteri	4.0	4.8	5.9	2,010	24
Uterus	13.1	9.7	9.4	4,434	42
Ovary	6.7	5.6	5.5	2,500	20
Prostate	64.5	72.3	72.4	33,428	312
Testis	2.8	2.2	2.5	887	11
Urinary Bladder	20.6	19.4	18.8	8,453	69
Kidney & Renal Pelvis	15.2	20.2	21.9	9,054	87
Brain & other nervous system	6.5	5.9	6.7	2,577	28
Thyroid	12.4	10.7	6.9	4,671	30
Hodgkin lymphoma	2.7	2.9	3.3	1,241	14
Non-Hodgkin lymphoma	19.7	20.0	19.8	8,758	79
Myeloma	6.3	7.0	8.1	3,064	33
Leukemia	13.4	12.7	10.1	5,479	41

* Average annual rates per 100,000, age adjusted to the U.S. 2000 standard.
Cases are assigned to the parish of residence, not where they were diagnosed or treated.

** U.S. rates from the Surveillance, Epidemiology and End Results (SEER) Program of the National Cancer Institute

The Louisiana Tumor Registry is supported by the SEER Program, the National Program of Cancer Registries (CDC), LSU Health Sciences Center-New Orleans, and host institutions.

More about the Louisiana Tumor Registry can be found at: http://sph.lsuhsc.edu/louisiana-tumor-registry

Message

From: Burhop, Anna [anna.burhop@bracewell.com]
Sent: 1/9/2018 7:17:14 PM
To: Dravis, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ece53f0610054e669d9dffe0b3a842df-Dravis, Sam]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
CC: Krenik, Edward [edward.krenik@bracewell.com]; Lee, John [john.lee@bracewell.com]
Subject: Chloroprene RfC
Attachments: Letter to EPA 20170626.pdf

Flag: Follow up

Samantha and Brittany,

Since joining Bracewell, I have been working on a Request for Correction of the 2010 IRIS Review of Chloroprene. The IRIS Review contains errors and flawed science. We have met with ORD and the Office of the Administrator on this, and would like to brief you both on this as well. Do y'all have some time later this week or next for my colleagues, Ed Krenik and John Lee, and I to come meet with you?

Attached is the letter DPE sent to Administrator Pruitt last June explaining the request. I am also happy to share the full RfC with you.

Please let me know what times may work for your schedule. Feel free to give me a call if you have questions at 202.828.1728

Thank you!

Anna

ANNA BURHOP
Principal
anna.burhop@policyres.com
T: +1.202.828.1728 | F: +1.800.404.3970

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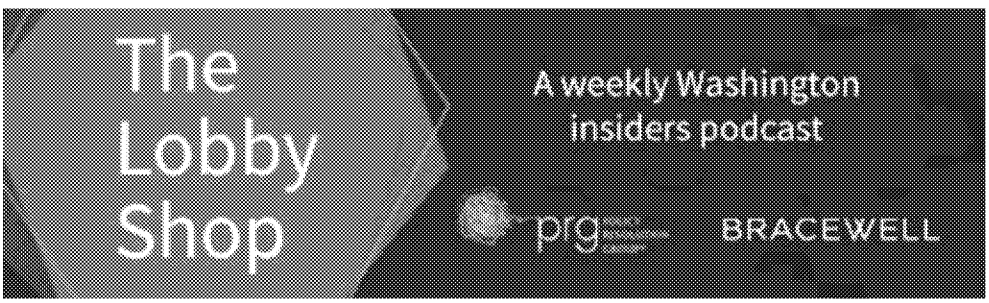
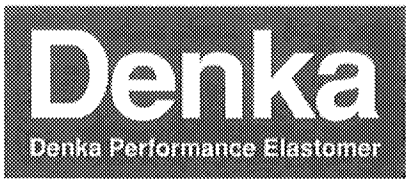




Denka Performance Elastomer LLC
560 Highway 44
LaPlace, LA 70068

June 26, 2017

The Honorable Scott Pruitt
Administrator
U.S. Environmental Protection Agency Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington, D.C. 20460

Re: Request to Withdraw and Correct the 2010 IRIS Review of Chloroprene

Dear Administrator Pruitt:

I write on behalf of Denka Performance Elastomer LLC (DPE) in support of the request that the U.S. Environmental Protection Agency (EPA) withdraw and correct its Integrated Risk Information System (IRIS) Toxicological Review of Chloroprene (EPA/635/R-09/010F, 2010) (the 2010 IRIS Review). The errors in the 2010 IRIS Review threaten the very survival of DPE's Neoprene production facility in LaPlace, Louisiana (Facility). In particular, based on those errors and EPA's subsequent flawed determinations concerning the risks caused by Facility emissions, EPA is making stringent air pollution control demands concerning the Facility that are technologically impossible to achieve. EPA must expeditiously apply good science in this matter in order to alleviate the public's undue concerns about the risks associated with this Facility and to prevent further significant damage to DPE's business.

Key conclusions of the 2010 IRIS Review are not based on the best available science or sound scientific practices. First, the 2010 IRIS Review rejected the findings of the strongest available epidemiological study, which concluded that there is no increased risk of cancer in workers exposed to chloroprene (some of the study cohorts actually exhibited a *lower* risk of cancer than the control population). Rather than accepting the overall study conclusions, the 2010 IRIS Review relied on select statistically non-significant comparisons of cancer incidence rates among subgroups of the larger epidemiology study to bolster its classification of chloroprene as "likely to be carcinogenic to humans." Second, the 2010 IRIS Review is flawed because it relied on laboratory animal studies, and then used the results for the most sensitive laboratory animal – female mice – as the basis for a series of overly conservative calculations to develop the human inhalation unit risk (IUR). Contrary to sound scientific practice, the 2010 IRIS Review ignored the known differences between humans and a select strain of female laboratory mice, and relied on results in those female mice to estimate an IUR for humans. Third, the 2010 IRIS Review gives chloroprene, which EPA designates only as a "likely" and not a "known" human carcinogen, the fifth highest IUR estimate of any similar chemical, including known human carcinogens, in the IRIS database. DuPont, the former Facility owner, provided similar information and analysis to EPA in comments on the draft IRIS Review, which comments were rejected in 2010. DPE's Request for Correction and the Ramboll Environ report provide new information and weight-of-evidence review not available in 2010.

Denka Performance Elastomer LLC
560 Highway 44
LaPlace, LA 70068

After EPA published the 2010 IRIS Review, the National Academies of Sciences' National Research Council (NRC) recommended major reforms in the IRIS process. Congress has repeatedly instructed EPA to implement the NRC's recommendations, and EPA has advised Congress that it is doing so. The 2010 IRIS Review is plagued with flaws similar to those that gave rise to these reform initiatives, and it is extremely important that the 2010 IRIS Review now be corrected in light of its scientific and procedural deficiencies.

These issues are more fully explained in DPE's Request for Correction and in the supporting toxicological and epidemiological expert review prepared by prominent scientists with the consulting firm of Ramboll Environ: Drs. Kenneth Mundt, Robinan Gentry, and Sonja Sax. Their report is entitled *Basis for Requesting Correction of the U.S. EPA Toxicological Review of Chloroprene*, dated June 2017 ("the Ramboll Environ Report," and attached hereto). The Ramboll Environ Report identifies multiple substantive errors in the 2010 IRIS Review and demonstrates that if chloroprene is to be treated as a possible human carcinogen, the 2010 IRIS Review establishes an IUR that is 156 times too high.

By way of background, DPE acquired the Neoprene Facility from DuPont on November 1, 2015. Neoprene is a synthetic rubber utilized in a wide variety of applications, including laptop sleeves, orthopedic braces, electrical insulation, and automotive fan belts. DPE is the only manufacturer of Neoprene in the United States. The Facility is a commercial mainstay of LaPlace, Louisiana. With an annual payroll of $33 million, DPE directly employs 200-250 people in manufacturing jobs and regularly employs between 125 and 150 contractors. DPE also has created 16 new corporate jobs. Additionally, DPE is investing and upgrading the Facility, including taking new measures to reduce its environmental footprint and improve its productivity and competitiveness.

The base feedstock for Neoprene is chloroprene. The Facility's air permits authorize it to emit chloroprene, and the Facility operates in compliance with those permit limits. However, shortly after DPE's acquisition of the Facility, on December 17, 2015, EPA publicly released its 2011 National Air Toxics Assessment (NATA), which identified the Facility as creating the greatest offsite risk of cancer of any manufacturing facility in the United States. The NATA findings concerning the Facility are based on the scientifically unwarranted and outdated 2010 IRIS Review and the emission profile of the Facility.

Following the public release of the NATA, EPA and the Louisiana Department of Environmental Quality (LDEQ) pressed DPE to reduce emissions to achieve an extraordinarily miniscule ambient air target concentration of 0.2 $\mu g/m^3$ for chloroprene on an annual average basis (which is intended to reflect a 100 in 1,000,000 rate of potential excess cancers in a population exposed to such concentrations continuously for 70 years). The 0.2 $\mu g/m^3$ target is based on a risk assessment that applied the erroneous and scientifically unsubstantiated IUR from the 2010 IRIS Review, and the target reflects more than a four thousand-fold reduction in the applicable Louisiana 8-hour ambient standard for chloroprene. Ramboll Environ's expert scientific opinion is that the appropriate risk-based ambient target should be 156 times larger or 31.2 $\mu g/m^3$. There is no agency rule or even proposed rule requiring the attainment of the 0.2 $\mu g/m^3$ target, yet EPA has advised DPE, LDEQ, and the public that 0.2 $\mu g/m^3$ is the appropriate target.

As a result of the flawed science embodied in the 2010 IRIS Review, and as a result of the NATA findings and the Facility's emission profile, DPE has suffered extraordinary hardship in a number of ways.

Denka Performance Elastomer LLC
560 Highway 44
LaPlace, LA 70068

First, despite DPE's concerns about the science behind the 2010 IRIS Review, DPE is currently spending more than $18 million on new pollution controls. On January 6, 2017, DPE entered into an Administrative Order on Consent with LDEQ to reduce chloroprene emissions by approximately 85% below the level of the Facility's 2014 emissions. DPE estimates that the capital cost of these emission reduction devices is approximately $18 million, and the devices will cost hundreds of thousands of dollars per year to operate. Even though DPE is installing the most advanced air pollution controls available, it will still not be able to meet the stringent 0.2 $\mu g/m^3$ target.

Second, because the 2010 IRIS Review is flawed, EPA's very public announcements arising out of that Review and the NATA have created unnecessary public alarm. For example, after issuing the NATA, EPA created a public webpage specifically addressing DPE's chloroprene emissions.[1] Moreover, environmental activists and plaintiffs' lawyers have had numerous meetings in the community about DPE, all based on the faulty assumption that 0.2 $\mu g/m^3$ is the "safe" level for chloroprene. Further, a local citizen's group has formed and has been handing out misleading flyers and protesting near DPE's Facility. The erroneous IUR in the 2010 IRIS Review and the resulting NATA findings have caused DPE enormous reputational damage.

Third, as a result of the NATA findings, EPA Region 6 asked the National Environmental Investigations Center (NEIC) to investigate the regulatory compliance status of the Facility. NEIC sent a team of inspectors to the Facility from June 6-10, 2016, approximately seven months after DPE's acquisition. To be clear, DPE fully respects the important function of the EPA in enforcing environmental requirements. It is simply a fact, however, that as a result of the erroneous IUR and the NATA findings, EPA has initiated an enforcement proceeding against DPE and has devoted an extraordinary amount of resources from the Department of Justice, EPA headquarters, EPA Region 6, and NEIC to developing and pursuing the issues in the NEIC report.

Finally, since acquiring the Facility in November of 2015, DPE's relatively small management team has been buffeted by continuous environmental regulatory demands resulting from the erroneous IUR and the NATA findings. In addition to Facility operation, DPE staff has been in non-stop meetings and negotiations with EPA and LDEQ. DPE's legal and consulting expenses have been enormous, in the millions of dollars. Underlying all of these expenses and burdens on DPE is the erroneous IUR in the 2010 IRIS Review, as applied in the NATA risk assessment.

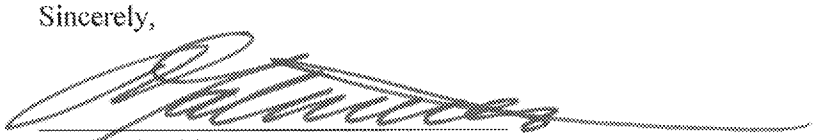
DPE needs EPA's assistance in the expeditious application of good science to this matter. In meetings with EPA in 2016 concerning the need to correct the 2010 IRIS Review, EPA officials advised DPE that EPA's "queue is full". DPE respectfully requests that EPA review the science underlying the 2010 IRIS Review, withdraw the erroneous IUR, and develop a more accurate toxicological review of chloroprene. We are confident that the Ramboll Environ Report will lead you to these conclusions. Without

[1] *See* https://www.epa.gov/la/laplace-louisiana-background-information.

Denka Performance Elastomer LLC
560 Highway 44
LaPlace, LA 70068

this relief, it is uncertain whether DPE will be able to reduce emissions sufficiently to satisfy agency demands, or even continue operation.

Sincerely,



Koki Tabuchi
President and Chief Executive Officer
Denka Performance Elastomer LLC

Message

From: Rock Zierman [rock@cipa.org]
Sent: 4/13/2017 10:28:32 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
CC: 'Pete Regan' [pregan@depausa.org]; Willie Rivera [willie@cipa.org]
Subject: EPA Region 9 Visit
Attachments: Summary of AE Submittal 032117.pdf; Aquifer Exemption Review in California 4-13-17.docx

Brittany—

Thanks so much for taking the time to talk by phone with us concerning the injection well issue here in California. Last week, we had the pleasure of meeting with Mr. Pruitt while we were in DC. We did not get deep into the details of our issue, but did discuss the visit of EPA personnel to CA that you mentioned. CIPA would welcome the opportunity to meet with those tasked with visiting Region 9, either a short meeting in SF or if they desire, we can take them on a tour of some stakeholder sites. Please let us know when the trip will occur and we look forward to getting the opportunity to meet with them.

Please find attached both the updated memo on the UIC issue and the updated status matrix that we discussed on our call. If you have any questions, please don't hesitate to contact me.

Best,

Rock Zierman
Chief Executive Officer
California Independent Petroleum Association
1001 K Street, 6th Floor
Sacramento, CA 95814
916-447-1177 P
916-447-1144 F
rock@cipa.org

Aquifer Exemption Review in California

In California, like many other oil producing regions, the vast majority of the fluid that comes out of production wells is brackish water comingled with oil and gas. Typical volumes have 97% water and only 3% oil and natural gas. The oil and natural gas are removed and sold and the produced water is reinjected back into the ground, usually back into the very formation from where it was produced, but cleaner than when it came out since the oil and gas have been removed.

In 2010, USEPA Region 9 directed the California Division of Oil, Gas and Geothermal Resources (DOGGR) to update the boundaries for underground aquifers used for the re-injection of produced water in more than 50 oil fields throughout California. The federal Safe Drinking Water Act requires any aquifer with less than 10,000 Total Dissolved Solids (TDS) water to be formally exempted by the USEPA in order for injection to be allowed, even in oil bearing aquifers. The original boundaries were adopted in the early 1980s and much more is now known about the geological boundaries of the underground aquifers. DOGGR had permitted injection wells outside of the original boundaries since the fluid was going into already exempted aquifers. USEPA told the state that they should have applied for expanded boundaries before permitting the wells. While industry disagrees with this analysis, we have been working hard to get EPA relevant data to complete the review.

All Aquifer Exemption (AE) applications are being completed using criteria established by the EPA, and, for several years now, the industry has been working with DOGGR, the State Water Board and the EPA to complete Aquifer Exemption applications for several oil fields/formations in California. At last count, there are over 40 applications now in the hands of these state agencies for review. State regulations adopted to complete these updates require each application go through a thorough review and approval by both DOGGR and the State Water Board before being forwarded to the EPA for final sign off. Specifically, each application must reach concurrence between DOGGR and State Water Board on confinement on the injected fluid, proper control of fluids, and each must show no impacts to potential sources of drinking water. This process also includes extensive public comment and hearings held in the area where the field is located. Individual operators have spent countless hours and significant resources in preparing each application.

To date, of the 43 applications currently under review, only 5 have been forwarded by the state to the USEPA and USEPA has approved 3 of them. The remaining AEs are expected to be forwarded to the USEPA in the next couple of months. The state adopted in state statute a February 15th, 2017 deadline which requires an Aquifer Exemption application have sign off by EPA in order to continue operating past February. Obviously, that deadline has passed. The state has said they will not enforce the deadline for most AE applications. However, that is likely to be challenged by environmental NGOs. This poses a huge problem for the industry and for California production. Production losses in the state would be over 105,000 barrels of oil per day if this injection is not allowed, all because of an artificial paperwork problem. These barrels would have to be tankered into California's refineries, increasing both gasoline prices and dependence on foreign oil. Industry has obtained a court-ordered preliminary injunction against the state's ability to enforce the February 15 deadline.

Action item needed: To date, the USEPA has worked diligently to review the AE applications sent to it by the state. However, only 5 of the 43 applications have been forwarded to EPA. The remainder will land on EPA desks soon. A review of Region 9's staff resources dedicated to this important process should be conducted and direction given regarding the importance of timely review of applications. Also, the appointment of a Region 9 administrator (currently vacant) would provide oversight on this issue. CIPA has forwarded a recommendation of a well-qualified candidate for that appointment.

Catalyst
ENVIRONMENTAL SOLUTIONS

Technical Memorandum

Date: March 21, 2017

To: Rock Zierman, CIPA

From: Megan Schwartz

RE: **Status Update of Aquifer Exemption Packages**

The following presents an updated summary of the status of aquifer exemption applications for those fields/zones which will require an exemption in order to continue injection operations.

Summary Table

Approved	EPA Review	Public Review Completed	Public Review in Progress	Public Review Pending	SWRCB Review	HQ Review	Local District Review	Still in Preparation
3	2	2	2	4	19	0	6	5

Aquifer Exemptions Approved by EPA

Oilfield	Formation	Date Submitted	Operator	Exemption Criteria	Well Type	Date Approved by EPA
Fruitvale	Santa Margarita, Etchegoin, Chanac	November 9, 2016	Hathaway, Summit Energy	A, c	EOR WD	February 9, 2017
Round Mountain	Vedder	November 30, 2016	Macpherson	A, b1, b2	EOR WD	February 9, 2017
Tejon	Transition	December 2, 2016	CRC	A, b1	EOR	February 9, 2017

Aquifer Exemption Submittals from DOGGR to EPA

Oilfield	Formation	Date Submitted	Operator	Exemption Criteria	Well Type	Status
Arroyo Grande	Dollie Sands	February 8, 2016	SPR		EOR WD	Package will be put out for another public review (likely 15-day review period without a hearing). Prior to

						initiating another public review, DOGGR and Operator will hold an informal meeting with EPA to discuss issues. Following public review, EPA will continue its review of the exemption package.
Mt. Poso	Vedder	February 15, 2017	Macpherson	A, b1	WD	Under review by EPA. No timeline provided by EPA for completion of review.

Aquifer Exemptions – Public Review Period Completed

Oilfield	Formation	Operator	Exemption Criteria	Well Type	Status
Livermore	Greenville Sands	E&B Natural Resources	A, b1	WD	Public review period ended January 25, 2017. DOGGR working on response to comments received.
San Ardo (includes McCool Ranch and Monterey County wells)	Lombardi and Aurignac	Chevron, Trio Petroleum, Aera	A, c	EOR WD	Initial Public review period ended February 16, 2017. Review period extended to March 3, 2017. DOGGR working on response to comments received.

Aquifer Exemptions under Public Review

Oilfield	Formation	Operator	Exemption Criteria	Well Type	Status
Kern Front	Vedder	CRC, Hathaway	A, c	EOR/WD	Preliminary concurrence letter from SWRCB submitted to DOGGR on February 13, 2017. Public review period notice published March 20, 2017. Public hearing to be held April 19 at 4PM.
Jasmin	Cantleberry	Hathaway	A, b1	EOR/WD	Submitted to SWRCB on September 28, 2016. Preliminary concurrence letter to DOGGR on February

					6, 2017. Public review period notice published March 20, 2017. Public hearing to be held April 19 at 4PM.

Aquifer Exemptions – Preliminary Concurrence Received, Public Review Pending

Oilfield	Formation	Operator	Exemption Criteria	Well Type	Status
Lynch Canyon	Lanigan Sands	Eagle Petroleum	A, b1	EOR	Preliminary concurrence letter to DOGGR on February 3, 2017. Public review period anticipated to begin in March with hearing late April/early May.
Sespe	Basal Sespe	Seneca	A, b1	WD	Preliminary concurrence letter to DOGGR on February 3, 2017. Public review period anticipated to begin in March with hearing late April/early May. No update on approval of public materials
Poso Creek	Etchegoin, Chanac	Linn, E&B	A, b1	EOR	Submitted to SWRCB on September 7, 2016. Preliminary concurrence letter to DOGGR on February 15, 2017.
Poso Creek	Chanac	Hathaway	A, b1	EOR	Submitted to SWRCB on September 7, 2016. Preliminary concurrence letter to DOGGR on February 15, 2017.

Aquifer Exemptions Under Review at State Water Resources Control Board

Oilfield	Formation	Operator(s)	Exemption Criteria	Well Type	Status
Kern Front	Chanac	CRC, Hathaway	A, b1	EOR/WD	Submitted to SWRCB on September 12, 2016. SWRCB submitted questions to DOGGR on October 23, 2016. DOGGR responded December 22. DOGGR is working with operator to provide additional information for SWRCB review.
Elk Hills (Phase 1)	Tulare	CRC	A, b3, c	WD	Submitted to SWRCB July 28, 2016 and SWRCB continues its review.
McKittrick	Tulare	SPR, Linn, Chevron, Aera, E&B Natural Resources	A, b1	Tulare – EOR/WD Other formations - WD	Submitted to SWRCB on July 19, 2016. DOGGR submitted responses to questions from SWRCB on October 20, 2016. DOGGR met with SWRCB on December 2, 2016. SWRCB continues its review.
Midway-Sunset	Tulare, Miocene Shale, Potter, Spellacy, Lower Antelope Sands	SPR, Linn, Chevron, Aera, TRC, Holmes Western, Seneca	A, b1, c	EOR WD	Submitted to SWRCB on August 11, 2016. Inland District and SWRCB discussed package via teleconference on October 6, 2016. SWRCB still reviewing materials.
Kern River	Kern River	Chevron, E&B, Kern River Holdings, Gray Development	A, b1	EOR	Submitted SWRCB on July 27, 2016. DOGGR received questions from SWRCB on August 16, 2016 concerned about

Oilfield	Formation	Operator(s)	Exemption Criteria	Well Type	Status
					water wells in the area. DOGGR submitted response to SWRCB questions on November 4, 2016. SWRCB review continues.
Cymric	Tulare, Tembior, Eocene Sands	SPR, Linn, Chevron, Aera, E&B Natural Resources, TRC	Tulare – a, b1, c Phacoides – a, b1	Tulare – EOR/WD Phacoides - WD	Submitted to SWRCB on July 19, 2016. A working meeting between DOGGR and SWRCB was held December 20, 2016. SWRCB continues to review.
Cat Canyon	Sisquoc	ERG	A, b1	EOR WD	Submitted to SWRCB on June 27, 2016. DOGGR received questions from SWRCB on the package on September 29, 2016. Operator completed well surveys, submitted to DOGGR and SWRCB. DOGGR submitted responses to SWRCB the week of February 20, 2017.
South Belridge	Tulare	CRC, SPR, Aera, Vaquero, Linn, E&B, West American Energy, Belridge Operating Company	A, b1, c	EOR WD	Submitted to SWRCB during the week of August 22, 2016. DOGGR received questions on the package from both the SWRCB and RWQCB on November 30, 2016 and submitted responses in January 2017.
Elk Hills (Phase 2)	Tulare	CRC	A, b3, c	WD	Submitted to SWRCB on August 23, 2016. DOGGR received

Oilfield	Formation	Operator(s)	Exemption Criteria	Well Type	Status
					questions from SWRCB and submitted responses in December 2016.
Lost Hills (Phase I)	Tulare	Chevron, Seneca, CRC, Aera	A, b1, c	EOR	Submitted to SWRCB on August 23, 2016. DOGGR received questions on the package from both the SWRCB and RWQCB on November 30, 2016 and submitted responses in January 2017. SWRCB continues review.
Lynch Canyon	Santa Margarita	Eagle Petroleum	A, c	EOR/WD	Submitted to the SWRCB week of August 28, 2016. Operator submitted revised water sampling plan on December 19, 2016 and additional detailed program for workover on December 21. SWRCB is reviewing the sample plan and DOGGR will work with operator to implement.
Coalinga/Jacolitos	Temblor	Seneca, Chevron, Aera, Holmes		EOR	Submitted to SWRCB in mid-September 2016. DOGGR received questions from the SWRCB on November 30, 2016 and submitted responses to SWRCB. Additional questions from SWRCB were received on January 6, 2017.

Oilfield	Formation	Operator(s)	Exemption Criteria	Well Type	Status
Edison Field	Pyramid Hill, Vedder combined, Chanac, Fruitvale, Santa Margarita	Hathaway, Naftex	A, b1	Santa Margarita – WD All other formations - EOR/WD	Submitted to SWRCB on September 19, 2016. DOGGR sent SWRCB a new Chanac chapter on December 6, 2016 which includes updated well information. DOGGR received additional questions on Chanac in February 2017 and is working on responses.
Zaca	Monterey	Greka, Towne Exploration, Amrich	A, b1	WD	Submitted to SWRCB on October 19, 2016. DOGGR is working with SWRCB on their review. SWRCB gave a presentation on their comments on December 14, 2016. DOGGR submitted responses to questions in February 2017.
Holser	Holser (Modelo)	Mirada Petroleum	A, b1	WD	DOGGR received questions from SWRCB in September 2016 and is working with operator on responses. DOGGR resubmitted to SWRCB the week of November 7, 2016. DOGGR submitted additional information to SWRCB on December 28, 2016. SWRCB continues their review.
North Belridge	Tulare	Aera	A, b1	WD, EOR	Submitted to SWRCB the week of November 7, 2016.

Oilfield	Formation	Operator(s)	Exemption Criteria	Well Type	Status
					DOGGR received questions from the SWRCB on November 30, 2016 and submitted responses in December 2016.
Lompoc (includes the wells in the Lompoc Main and NW areas)	Monterey	SPR	A, b1	WD	Submitted to SWRCB in December 2016.
Casmalia	Monterey	Sierra Resources, Greka, ERG	A, b3	WD	Submitted to SWRCB the week of January 9, 2017.
Oxnard	Pliocene tar (Vaca sand)	CRC, Peak Energy, Vaca Energy	A, b1	EOR	Submitted to HQ and SWRCB the week of February 12, 2017.

Aquifer Exemption Under Review at Local DOGGR Offices

Oilfield	Formation	Operator(s)	Exemption Criteria	Well Type	Status
Edison Field Northeast	Chanac	Hathaway	A, b1	EOR	Under review at local district. Operator submitted updated figures and text on September 19, 2016. DOGGR completed the water well search on September 28, 2016. Still under local review.
Kettleman Hills, North Dome	San Joaquin, Etchegoin	CRC	A, b3, c	WD	Submitted to District office on August 10, 2016. Still under review at the local district. Operator is still working on the package.
Cat Canyon, Gato Ridge	Monterey, Santa Margarita	BE Conway, ERG, Greka, Aera, RMR Resources	A, b1	WD	Submitted to local district August 1, 2016. Revised packages submitted on August 8, 12, and 17, October 5 and November 11, 2016. Request for changes sent to Operator on February 1, 2017; Operator is currently revising the package. Review will be completed by the Inland District.
Rosedale Ranch	Chanac	Freedom Oil	A, b1	WD, EOR	Submitted to District office on August 15, 2016. District office requested operator revise the

					package. Operator is still working on revisions to the package.
Kreyenhagen		Solimar Energy		WD	Submitted to District office on August 15, 2016. Still under review at the local district.
Chico Martinez	Lower Tulare	Chico-Martinez Oil	A, b1, c	WD	Submitted to the District office. District office is working with operator to provide additional support material.

Aquifer Exemption Packages Still in Progress, Not Yet Submitted

Oilfield	Formation	Well Type	Operator(s)
Mountain View	Kern River, Chanac	EOR/WD	Sunray, Bennett Petroleum, Citadel
Kern Bluff	Chanac, Transition, Santa Margarita, Olcese, Vedder	EOR/WD	Citadel Exploration
Round Mountain South	Olcese		Pace Development
Lost Hills (Phase II)	Tulare	WD	CRC, Seneca, Aera, Chevron
Richfield		WD	Richfield Oil

Message

From: Amelia Berger [amelia.berger@bracewell.com]
Sent: 8/13/2018 9:34:08 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs from RFS Flaws In Reference to Docket ID No. EPA-HQ-OAR-2017-0091

Dear Brittany Bolen,

The time is now to help prevent a massive loss of good-paying American jobs. Refinery workers across the country are potentially at risk if U.S. independent refiners go out of business due to the skyrocketing costs associated with the Renewable Fuel Standard (RFS). The EPA currently implements the RFS in a way that makes all U.S. refiners responsible for ensuring that certain levels of renewable fuels are blended into gasoline, even if they do not have the capabilities to do such blending.

This nonsensical set-up gives large integrated oil companies that blend more fuel than they refine, coupled with big convenience store gasoline chains (who actually do much of the blending), a competitive market advantage. These companies gather valuable credits from the U.S. government for each gallon of renewable fuel they blend into gasoline produced by independent refiners, who do little or no blending themselves. Independent refiners are then forced to purchase those credits, often at astronomical prices, to comply with the RFS. These credits contributed to the bankruptcy of PES. Other refiners are at risk due to this backwards regulation, with 75,000 - 150,000 U.S. workers potentially impacted.

Finally, EPA should reduce the renewable fuel volumes to a level all engines and infrastructure can handle, which will help reduce the cost to refiners.

Please help save our jobs and make this right. We ask that you take action to reduce the renewable fuel volumes and address the dysfunctional RFS credit system in a way that fixes this inequity and preserves the viability of America's refining sector.

Thank you.

Sincerely,
Amelia Berger
1324 Euclid St NW Apt 208
, DC 20009

Message

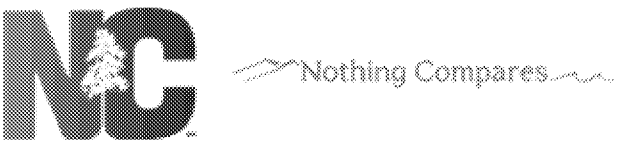
From: Pendola, Tony [tony.pendola@ncdenr.gov]
Sent: 8/9/2018 7:26:44 PM
To: sbeap_main@nationalsbeap.org
CC: Allocco, Marcia [marcia.allocco@ncdenr.gov]; Ragan, Jamie [jamie.ragan@ncdenr.gov]; Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Wilson, Holly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=208c5fea61f24fefbfd9bb7299f830c1-HWILSON]
Subject: Webinar: State Strategies to Help Businesses Launch and Expand

Pew had trouble sending this out and asked that I share it with the SBEAPs. I have been given a couple minutes to introduce our program to the attendees, but the report doesn't mention us much. It mostly encourages offering compliance assistance. Feel free to share it with your state compliance assistance folks, trade associations, or others who might want to listen in.

Tony Pendola, PE
Small Business Ombudsman
Division of Environmental Assistance and Customer Service
Department of Environmental Quality
919 707 8112 office
877 623 6748 toll-free
tony.pendola@ncdenr.gov

sb.ncdenr.gov

1639 MSC
Raleigh, NC 27699-1600



From: Mirielle Burgoyne [mailto:mburgoyne@pewtrusts.org]
Sent: Thursday, August 9, 2018 1:50 PM
To: Pendola, Tony <tony.pendola@ncdenr.gov>
Subject: [External] Webinar: State Strategies to Help Businesses Launch and Expand

Tony,

Please feel free to share the following webinar invitation (attached and below). We would love to have some of the SBEAPs join us!

Thanks so much!

Mirielle Burgoyne
Senior Associate, Economic Development
The Pew Charitable Trusts
901 E Street, NW, Washington, DC 20004
p: 202-552-2157| e: mburgoyne@pewtrusts.org | www.pewtrusts.org

PEW

Webinar: State Strategies to Help Businesses Launch and Expand

REGISTER NOW

The Pew Charitable Trusts invites you to preview our findings for our forthcoming report **"State Strategies to Help Businesses Launch and Expand"** on a private webinar for key contributors to the report's research.

State Strategies to Help Businesses Launch and Expand

Wednesday, August 15, 2018

2:00 PM EDT

Register here

Panelists:

- Melissa Maynard, Officer, State Fiscal Health, The Pew Charitable Trusts
- Lauren Larson, Director, Colorado Office of State Planning and Budgeting
- Rob Woods, Director, Arizona Governor's Transformation Office

Our new report examines ways states can improve how they regulate businesses in order to help achieve their economic development objectives. States are demonstrating that, by administering rules more efficiently and partnering with the private sector, they can substantially lower compliance costs for businesses while simultaneously achieving important goals such as protecting the environment and public health.

An advance copy of the report will be emailed to all registered webinar participants shortly before the webinar begins.

Thank you for being so gracious with your time and expertise as we researched state regulatory operations for this report; we're deeply indebted to your generosity and knowledge. We hope you can join us on August 15 to hear about the final report, and we look forward to continuing to work with you in the future. Please feel free to contact me with any questions about our research, and thanks again for your invaluable input.

Sincerely,

Melissa Maynard
The Pew Charitable Trusts

REGISTER NOW

The linked image cannot be displayed. The file may have been moved, renamed, or deleted. Verify that the link points to the correct file and location.

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PEWTRUSTS.ORG

Learn more about The Pew Charitable Trusts and our Mission:

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901 E Street NW, Washington, DC 20004-2008

Contact | Privacy

Message

From: Lacey, Pam [PLacey@aga.org]
Sent: 5/4/2018 4:22:47 PM
To: Dunham, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a9444681441e4521ad92ae7d42919223-SDUNHAM]; Tsirigotis, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d19c179f3ccb4fadb48e3ae85563f132-PTSIRIGO]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Gunning, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f65040017f05429aa05572f096a50463-PGUNNING]; Snyder, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fafc36d202f4de3a925e1df708edd9e-Snyder, Car]; Harvey, Reid [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8ec31caad5048db83f210032847de32-RHARVE02]
Subject: FW: Government Rate for World Gas Conference June 25-29 2018 in DC - Young Professionals Program: Government rate now available!

All – Please let your young staff members (40 or under) know about this special opportunity to attend the World Gas Conference & Exhibit June 25-29, 2018 in Washington D.C. through the Young Professionals Program on a Government Rate. Information is provided below.

This is a once-in-a career opportunity to learn from technical, policy and operations experts and view technologies and equipment from natural gas production, pipeline, storage, distribution and end use from across the globe – including innovative renewable natural gas (RNG). The last time the World Gas Conference was held in the United States – let alone right here in Washington DC - was 30 years ago, and the time before that was also 30 years before that. It was held in Paris in 2015, and three years from now it will be in Seoul, Korea.

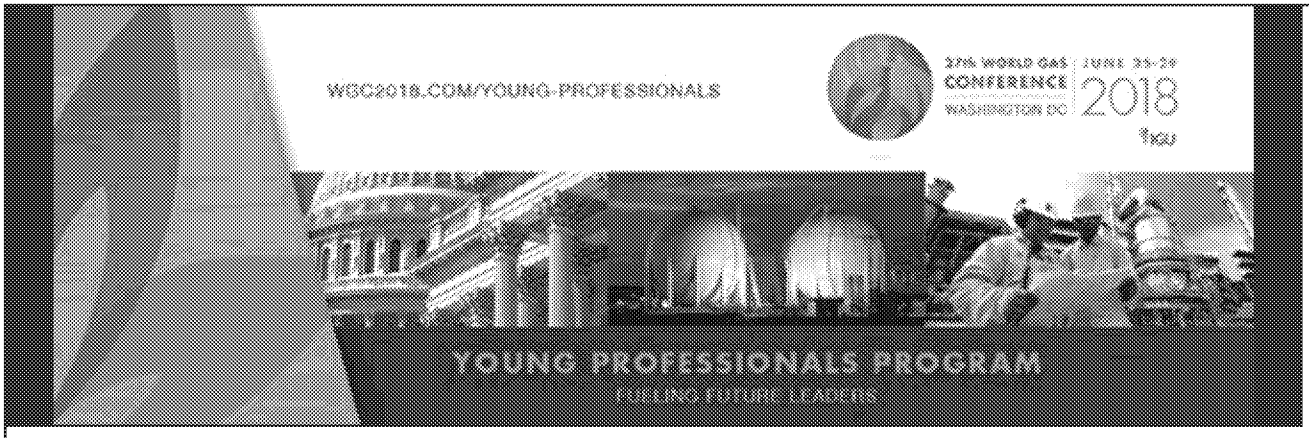
The regular fee for non-government attendees (and over 40 years old) is $4,000. The non-government registration fee for the Young Professionals Program is $900. And the Government Rate for Young Professionals is just $450.

If you have any questions, please let me know. And please feel free to share this Government Rate opportunity with any young people you know at other agencies who might be interested.

Best regards, Pam

Pamela A. Lacey | Chief Regulatory Counsel
American Gas Association
400 N. Capitol St., NW | Washington, DC | 20001
P: 202-824-7340 | M: 202-809-6565 | F: 202-824-9190 | placey@aga.org

From: ypp@WGC2018.mmsend.com [mailto:ypp@WGC2018.mmsend.com] **On Behalf Of** ypp@WGC2018.com
Sent: Friday, May 04, 2018 9:38 AM
To: Ashley Duckman <ADuckman@aga.org>
Subject: WGC 2018 Young Professionals Program: Government rate now available!



GOVERNMENT RATE NOW AVAILABLE

A government rate of $450 is now available for those interested in attending the WGC 2018 Young Professionals Program. Do not miss your opportunity to attend this event!

In conjunction with the World Gas Conference (WGC 2018), the American Gas Association will host the ***Young Professionals Program (YPP).*** To be held June 27-29, 2018 in Washington D.C., the YPP will provide an excellent opportunity for promising young professionals in the energy sector, as well as other stakeholders, to learn from top leaders in the natural gas industry and network with their peers from around the world.

The program is seeking global participants who are passionate about learning and continuing to contribute their skills and leadership abilities to the energy sector. The agenda will include engaging panel discussions that will focus on critical industry issues such as *Global Perspectives on the Future of Natural Gas* and *Planning for a Low Carbon Future.* As well, the agenda will feature several sessions focused on professional development topics including *Preparing for an Evolving Career* and *Recruiting the Next Generation of Energy Leaders*. In addition to formal conference programming, YPP participants will benefit from access to the WGC 2018 exhibit hall, where they will have the opportunity to experience one-on-one interactions with exhibitors from across the globe.

The program is open to all employees and stakeholders in the energy industry who are 40 years of age or younger. A government rate of $450 is now available for those who qualify. Registration includes YPP programming, access to the

WGC 2018 exhibition floor and several networking events, including an evening reception at AGA Headquarters.

An updated program agenda can be found by clicking here.

Note that the YPP is limited to the first 200 registrants—and spots are filling quickly! Register now before it's too late.

For more information on the event, including a link to register and secure your hotel accommodations, please visit this link.

Also, follow us on Twitter @WGC_YPP2018 or LinkedIn for frequent updates and shared content.

Ashley Duckman | Program Coordinator, Young Professionals Program
202-824-7212 | YPP@wgc2018.com
400 North Capitol Street, NW | Washington, DC 20001

Message

From: Wildeman, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=05DD0AF69BFA40429E438B7646502B99-WILDEMAN, A]
Sent: 6/5/2018 11:23:42 AM
To: Caravelli, Margaret [mcaravelli@balch.com]
CC: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Penman, Crystal [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93662678a6fd4d4695c3df22cd95935a-Penman, Crystal]
Subject: RE: Water Related Rulemaking

Hi Margaret,
I would be happy to discuss 316(b) with you. This week won't work for my calendar, but I've copied Crystal Penman on this email and she can help get something scheduled for next week.
Best,
Anna

From: Caravelli, Margaret [mailto:mcaravelli@balch.com]
Sent: Monday, June 4, 2018 4:14 PM
To: Wildeman, Anna <wildeman.anna@epa.gov>
Cc: Bolen, Brittany <bolen.brittany@epa.gov>
Subject: Water Related Rulemaking

Hi Anna:
Reaching out to you in follow up to a brief conversation I had with Lee Forsgren last week. It's my understanding this is your first week or so at EPA HQ. By way of introduction I am a former House & Senate Committee Senior Counsel that handled the Clean Air Act.
I've included Brittany Bolen from the Office of Policy on this email because the inquiry also relates to regulatory reform of which I know Brittany is involved. Brittany and I are former colleagues from the Senate Environment and Public Works Committee.

Currently, I work with clients that have an interest in the 316(b) and certain aspects of its applicability. Is it best to schedule a meeting with you to discuss the 316(b) rulemaking and interpretative matters? Do you have a scheduler?

Please let me know if my request needs to be directly elsewhere. My contact information is below in the signature line. Thank you in advance.

Regards,
Margaret Caravelli

BALCH
& BINGHAM LLP

Margaret Caravelli, Partner, Balch & Bingham LLP
601 Pennsylvania Avenue, NW • Suite 825 South • Washington, DC 20004-2601
t: (202) 661-6342 Ex. 6 e: mcaravelli@balch.com
www.balch.com

Message

From: Jamie Conrad [jamie@conradcounsel.com]
Sent: 2/2/2018 7:47:47 PM
To: David Wawer [DavidWawer@CPMA.Com]
CC: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Robert Helminiak [helminiakr@socma.com]; Tatiana Letcheva [TatianaLetcheva@CPMA.Com]
Subject: Re: Question: 2016 EPA Request to NTP to Conduct Toxicological Study of PCB-11
Attachments: James W. Conrad Jr..vcf

Flag: Follow up

Good idea. Good luck!

-- Jamie

James W. Conrad, Jr.
Conrad Law & Policy Counsel
910 17th St., NW, Suite 800
Washington, DC 20006-2606

202-822-1970
Ex. 6 (cell)
jamie@conradcounsel.com
www.conradcounsel.com

On Feb 2, 2018, at 2:30 PM, David Wawer <DavidWawer@CPMA.Com> wrote:

Dear Brittany,

During the previous Administration (late 2015 or early 2016), a request originated from unknown career staff at EPA to the NTP for a study of PCB-11 (see below). The NTP webpage incorrectly characterized the known uses, however - color pigment manufacturers do not intentionally use PCB 11 to produce color pigments. My efforts to communicate with a responsible person at NTP, to correct their mischaracterization of known uses, went into a "black hole". We also had several conversations with EPA staff in the Program Assessment & Outreach Branch of OPPT in 2016 to better understand the genesis of the original request from EPA to NTP. As recently as last year, OPPT staff could not provide copies of any official or unofficial communication between EPA staff and NTP requesting the PCB-11 study. Such communication would have outlined the rationale for requesting the study in the first place.

It's now early 2018, with no information forthcoming from NTP staff, and still no understanding why this study was requested by EPA career staff in the first place.

I realize your office has been dealing with mega-issues, and quite successfully, during the first year of the Trump Administration, and that this "small NTP project" is probably not on your radar screen. We believe there are very pertinent questions surrounding this project for which stakeholders/taxpayers should be informed.

Why was this project initiated in the first place in light of the fact there was no public threat to human health & the environment?
How many taxpayer dollars have been spent to date?
How many NTP staff resources have been assigned to this project?
When is it going to end, what is going to be the final cost to taxpayers, and what does one expect to gain in terms of public policy as a result of this activity?

In your leadership role at EPA, we request that you communicate with OPPT officials and NTP officials, in an effort to provide greater public transparency on this three-year old agency activity?

CPMA representatives would be glad to meet with you to provide further background information and answer any related questions you may have.

Thank you for your consideration in this matter.

Dave

Testing Status of 3,3'-Dichlorobiphenyl 15035

CASRN: 2050-67-1

Formula: C12-H8-Cl2

Synonyms/Common Names

- PCB 11

Known Uses

Yellow pigment

Chemical Properties

Toxicity Effects (HSDB)

Genetic Toxicology

- Salmonella (G15035) On Test
  - Lot/Batch: 26692

David Wawer, Executive Director
Color Pigments Manufacturers Association, Inc.
1400 Crystal Drive, Suite 630
Arlington,VA 22202
(571) 348-5106
www.pigments.org

Contact

Full Name: James W. Conrad Jr.
Last Name: Conrad
Middle Name: W.
First Name: James
Company: Conrad Law & Policy Counsel

Business Address: 910 17th Street, NW, Suite 800 Washington,, DC 20006-2606

Business Phone: 202 822-1970
Mobile Phone: Ex. 6

E-mail: jamie@conradcounsel.com

Message

From: Burhop, Anna [anna.burhop@bracewell.com]
Sent: 2/28/2018 5:25:49 PM
To: Burhop, Anna [anna.burhop@bracewell.com]
Subject: The Policy Resolution Group's 2018 Infrastructure Outlook Forum
Attachments: PRG Infrastructure Forum Program.pdf

Hope you can stop by the event tomorrow morning.

Having trouble reading this email? View it in your browser.

Join Bracewell's Policy Resolution Group, leaders from the legislative and executive branches, and industry executives for a morning of in-depth discussions on infrastructure policy and regulatory reform.

Thursday, March 1, 2018
8:30 AM – 12:00 PM EST
Coffee and light refreshments will be served.

Hart Senate Office Building
Room 902 (SH-902)
Washington, DC 20510

FEATURED SPEAKERS INCLUDE (PARTIAL LIST):

Senator Ted Cruz, TX

Congressman Will Hurd, TX-23

Paul Teller
Special Assistant to the President and House Special Assistant

Alex Herrgott
Associate Director for Infrastructure
Council on Environmental Quality

The Honorable Don Santa
President and CEO
Interstate Natural Gas Association of America

Michael Bellaman
President and CEO
Associated Builders and Contractors, Inc.

Chris Vieson
Deputy Staff Director
Committee on Transportation and Infrastructure

Host: Scott Segal
Co-Head
Policy Resolution Group, Bracewell

Click here to RSVP.
Space is limited. Please RSVP as soon as possible.
Your RSVP will be confirmed by email.

ANNA BURHOP
Principal
anna.burhop@policyres.com
T: +1.202.828.1728 | F: +1.800.404.3970

POLICY RESOLUTION GROUP | BRACEWELL LLP
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policyres.com | profile | download v-card

Host: Scott Segal
Co-Head, Policy Resolution Group

9:00 AM	**Congressman Will Hurd** TX- 23
9:30 AM	**Senator Ted Cruz** Texas
10:00 AM Panel 1: Energy Infrastructure & Regulatory Reform	**Alex Herrgott**, Associate Director for Infrastructure, Council on Environmental Quality **The Honorable Don Santa**, President and CEO, Interstate Natural Gas Association of America **Lisa Wood**, Vice President of Consumer Solutions, Edison Electric Institute **Anna Burhop**, Principal, Policy Resolution Group
10:45 AM Panel 2: Transportation & Construction	**Jim Ray**, Special Advisor to the Secretary for Infrastructure, Department of Transportation **Chris Vieson**, Deputy Staff Director, Committee on Transportation and Infrastructure **Michael Bellaman**, President and CEO, Associated Builders and Contractors, Inc. **Angela Styles**, Partner, Bracewell LLP
11:30 AM	**Paul Teller** Special Assistant to the President and House Special Assistant

Wi-Fi Network: SENATE_GUEST
Password: billofrights

#PRGLive

Message

From: Kane Hittle [kane.hittle@hollyfrontier.com]
Sent: 11/10/2017 2:14:18 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

Brittany Bolen,

The time is now to help prevent a massive loss of good-paying American jobs. The EPA currently implements the Renewable Fuel Standard in a way that makes all U.S. refiners responsible for ensuring that certain levels of renewable fuels are blended into gasoline, even if they do not have capabilities to do such blending.

This nonsensical set-up allows large integrated oil companies that blend more fuel than they refine and big convenience store gasoline chains (who do much of the blending) to collect valuable credits for the renewable fuel they blend into the pure gasoline they get from refineries. Independent refiners, who do little or no blending themselves, then end up purchasing those credits in order to demonstrate compliance with a process they have little control over. Small and independent refiners are at risk of going offline due to this backwards regulation, with 75,000-150,000 U.S. workers potentially impacted.

Please, help save our jobs and make this right. Please move the point of obligation for the RFS (Docket ID No. EPA–HQ– OAR–2017–0091) in a way that fixes this inequity.

Thank you.

Kane Hittle
324 Dominion Place
Heath, TX 75032

Message

From: Wyman, Christine [christine.wyman@bracewell.com]
Sent: 5/25/2018 11:42:28 AM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: RE: Follow Up
Attachments: ATT00001.txt

Flag: Follow up

Brittany – Thanks for taking the time on Wednesday to speak. I just left you a message with a read out from our meeting at the Corps. Happy to discuss more if you like.

-Christine

CHRISTINE WYMAN
Senior Counsel
christine.wyman@policyres.com
T: +1.202.828.5801 | F: +1.800.404.3970

BRACEWELL LLP
2001 M Street NW, Suite 900 | Washington, D.C. | 20036-3310
policyres.com | profile | download v-card

From: Bolen, Brittany [mailto:bolen.brittany@epa.gov]
Sent: Monday, May 21, 2018 5:45 PM
To: Wyman, Christine <christine.wyman@bracewell.com>
Subject: RE: Follow Up

Hi Christine –
I should have availability Wednesday. Please coordinate with Will Lovell (cc'd) to set this up.
Best,
Brittany

From: Wyman, Christine [mailto:christine.wyman@bracewell.com]
Sent: Monday, May 21, 2018 10:42 AM
To: Bolen, Brittany <bolen.brittany@epa.gov>
Subject: Follow Up

Hi Brittany – I wanted to follow up with a meeting that we had with you, Scott Segal, and a few folks from INGAA to discuss Section 401 of the Clean Water Act. By chance do you have time for a quick call this week? We could do anytime today, tomorrow from 12-2:30, Wednesday before noon or after 3pm, or Thursday morning.

Thanks!

Christine

CHRISTINE WYMAN
Senior Counsel
christine.wyman@policyres.com
T: +1.202.828.5801 | F: +1.800.404.3970

POLICY RESOLUTION GROUP | BRACEWELL LLP
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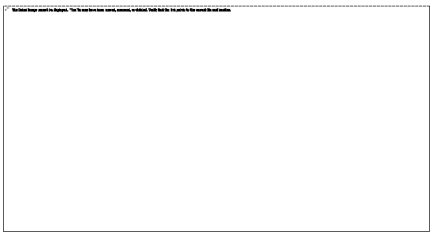

Message

From: Zeeshan Farooqui [mohammed.farooqui@hollyfrontier.com]
Sent: 10/31/2017 4:10:24 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Please, help save our jobs and make this right. Please move the point of obligation for the RFS (Docket ID No. EPA–HQ– OAR–2017–0091) in a way that fixes this inequity.

Thank you.

Zeeshan Farooqui
2828 North Harwood street
Dallas, TX 75201

Message

From: jennifer sanchez [jennifer.sanchez@hollyfrontier.com]
Sent: 11/6/2017 9:03:43 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Please, help save our jobs and make this right. Please move the point of obligation for the RFS (Docket ID No. EPA–HQ– OAR–2017–0091) in a way that fixes this inequity.

Thank you.

jennifer sanchez
10304 E 95th St North
owasso, OK 74055

Message

From: Michael Muse [michael.muse@hollyfrontier.com]
Sent: 2/23/2018 10:03:35 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

Brittany Bolen,

The time is now to help prevent a massive loss of good-paying American jobs. The largest refinery on the East Coast, owned by Philadelphia Energy Solutions (PES), just filed for bankruptcy due to the skyrocketing costs associated with the Renewable Fuel Standard (RFS). The EPA currently implements the Renewable Fuel Standard in a way that makes all U.S. refiners responsible for ensuring that certain levels of renewable fuels are blended into gasoline, even if they do not have capabilities to do such blending.

This nonsensical set-up allows large integrated oil companies that blend more fuel than they refine and big convenience store gasoline chains (who do much of the blending) to collect valuable credits for the renewable fuel they blend into the pure gasoline they get from refineries. Independent refiners, who do little or no blending themselves, are then forced to purchase those credits at astronomical prices in order to demonstrate compliance with a process they have little control over. More small and independent refiners are at risk of going offline due to this backwards regulation, with 75,000-150,000 U.S. workers potentially impacted.

Please, help save our jobs and make this right. Please take action to address out of control RIN prices in a way that fixes this inequity.

Thank you.

Michael Muse
3364 S. 141st E. Ave.
Tulsa, OK 74134

Message

From: John Cochlin [john.cochlin@hollyfrontier.com]
Sent: 10/31/2017 4:01:29 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

John Cochlin
2414 W 119th St. S.
Jenks, OK 74037

Message

From: Schneider, Jonathan [jonathan.schneider@stinson.com]
Sent: 9/22/2017 8:08:41 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
CC: Millar, Thomas R. [TMillar@willkie.com]; Lisa Levine [LLevine@eba-net.org]; Caplan, Stuart A. [Stuart.Caplan@troutmansanders.com]
Subject: FW: An invitation from the Energy Bar Association

Flag: Follow up

Dear Ms. Bolen:

As Vice President of the Energy Bar Association (EBA), I'd like to invite you to speak on a panel discussion at this year's Mid-Year Meeting, scheduled in Washington, D.C. for October 16-17. Forgive the late date for the invitation. We had invited Ms. Samantha Dravis initially, though she recently let us know she was unable to make the meeting. I think this is a good forum for the Administration to outline its plans, and it has been suggested to us that you would well represent the EPA.

EBA, as perhaps you know, is the preeminent association of legal professionals in the energy industry, comprising some 2000 attorneys and energy professionals nation-wide. We publish the Energy Law Journal, the nation's foremost legal publication in the energy industry, and sponsor several symposia throughout the year. The Mid-Year Meeting is one of our signature events, and generally attended by several hundred attorneys and policymakers. EBA's website is here: www.eba-net.org. A link to the Mid-Year program is here: http://www.eba-net.org/2017-eba-mid-year-energy-forum. Other Administration appointees speaking at the event are FERC Chairman Neil Chatterjee and recently appointed FERC Commissioner Robert Powelson. Is

The panel on which we invite you to speak will be held October 17, from 9-10:30 and will be held at the Renaissance Hotel (999 9th Street, NW). We would ask you, as you might imagine, to address the Administration's environmental policy as it affects the energy industry. Other panelists will include Andrew McKeon, President of the Northeast RGGI, and Ben Longstreth, with NRDC. I can promise you a high-level academic-oriented discussion, in which your participation would be most welcome. Kindly let us have your reaction, and please feel free to contact me with any questions.

With best regards,

Jon

Jonathan D. Schneider | Partner | Stinson Leonard Street LLP
1775 Pennsylvania Avenue NW, Suite 800 | Washington, DC 20006-4605
T: 202.728.3034 | M: **Ex. 6** | F: 202.572.9967
jonathan.schneider@stinson.com | www.stinson.com
Legal Administrative Assistant: Yvette Trammell | 202.572.9902 | yvette.trammell@stinson.com

Message

From: Lacey, Pam [PLacey@aga.org]
Sent: 8/22/2017 5:24:42 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Invitation to speak to AGA environmental committee (by phone link) Sept. 27, 2017 - afternoon

Flag: Flag for follow up

Dear Ms. Bolen – I look forward to our AGA-NGVA meeting rescheduled for Sept. 12. In addition, would you be available to speak via phone link about the Administration's regulatory reform plans to the AGA environmental committee on Wed. Sept. 27th ? The committee includes environmental policy directors and vice presidents from utilities around the country. The fall committee meeting will be held in Colorado on September 27th, and it would be wonderful if you could call in to speak to our members. Perhaps 12:30 pm Eastern Time? The time is flexible. Please let me know if you are available that day.

Best regards,

Pamela A. Lacey | Chief Regulatory Counsel
American Gas Association
400 N. Capitol St., NW | Washington, DC | 20001
P: 202-824-7340 | M: Ex. 6 | F: 202-824-9190 | placey@aga.org

Message

From: Matthew Cimino [matthew.cimino@hollyfrontier.com]
Sent: 10/31/2017 3:57:33 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

Brittany Bolen,

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This nonsensical set-up allows large integrated oil companies that blend more fuel than they refine and big convenience store gasoline chains (who do much of the blending) to collect valuable credits for the renewable fuel they blend into the pure gasoline they get from refineries. Independent refiners, who do little or no blending themselves, then end up purchasing those credits in order to demonstrate compliance with a process they have little control over. Small and independent refiners are at risk of going offline due to this backwards regulation, with 75,000-150,000 U.S. workers potentially impacted.

Please, help save our jobs and make this right. Please move the point of obligation for the RFS (Docket ID No. EPA–HQ– OAR–2017–0091) in a way that fixes this inequity.

Thank you.

Matthew Cimino
117 Mockingbird Lane
Georgetown, TX 78633

Message

From: Leslie Phipps [leslie.phipps@hollyfrontier.com]
Sent: 11/1/2017 4:01:37 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

Leslie Phipps
829 West 1935 South
Woods Cross, UT 84087

Message

From: Antonio Gomez [antonio.gomez@hollyfrontier.com]
Sent: 10/31/2017 3:49:59 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

Antonio Gomez
318 S 38th St
Artesia, NM 88210

Message

From: Chase Moses [chase.moses@hollyfrontier.com]
Sent: 11/1/2017 10:47:13 AM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Chase Moses
7769 W 118th St N
Sperry, OK 74073

Message

From: Rickey Applegate [rickey.applegate@hollyfrontier.com]
Sent: 11/3/2017 7:26:18 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

Rickey Applegate
941 Dalton Road
Cedar Vale, KS 67024

Message

From: Ryan Dubuisson [ryan.dubuisson@hollyfrontier.com]
Sent: 10/31/2017 3:47:26 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

Ryan Dubuisson
2320 Taylor St
Dallas, TX 75201

Message

From: Robert OBrien [robert.obrien@hollyfrontier.com]
Sent: 11/1/2017 12:19:27 AM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Robert OBrien
806 W. Monterrey Way
Artesia, NM 88210

Message

From: Jake Wyzard [jake.wyzard@hollyfrontier.com]
Sent: 11/3/2017 5:12:24 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

Jake Wyzard
1700 South Union Ave
Tulsa, OK 74107

Message

From: Erica Waugh [erica.waugh@hollyfrontier.com]
Sent: 10/31/2017 3:47:24 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Erica Waugh
5335 Bent Tree Forest Drive #225
Dallas, TX 75248

Message

From: Parrish Miller [parrish.miller@hollyfrontier.com]
Sent: 10/31/2017 10:59:36 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Parrish Miller
804 W Monterrey Way
Artesia, NM 88210

Message

From: Suzanne Thompson [suzanne.thompson@hollyfrontier.com]
Sent: 10/31/2017 3:47:21 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Please, help save our jobs and make this right. Please move the point of obligation for the RFS (Docket ID No. EPA–HQ– OAR–2017–0091) in a way that fixes this inequity.

Thank you.

Suzanne Thompson
1700 S Union Ave
Tulsa, OK 74107

Message

From: Chance Collins [chance.collins@hollyfrontier.com]
Sent: 11/3/2017 4:32:25 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Chance Collins
15437 Lake Road
Skiatook, OK 74070

Message

From: Robert Spencer [robert.spencer@hollyfrontier.com]
Sent: 10/31/2017 3:45:08 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Robert Spencer
1510 s. 21 st.
Artesia, NM 88210

Message

From: Terry Gary [Terry.Gary@hollyfrontier.com]
Sent: 11/3/2017 4:25:54 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Terry Gary
1933 west 65th street
Tulsa, OK 74132

Message

From: Patty Williams [patty.williams@hollyfrontier.com]
Sent: 10/31/2017 3:44:32 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Patty Williams
2828 N. Harwood, Suite 1300
Dallas, TX 75201

Message

From: Shana Olivas [shana.olivas@hollyfrontier.com]
Sent: 10/31/2017 3:42:31 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Shana Olivas
307 McArthur Ave
Artesia, NM 88210

Message

From: Natalie Dunn [natalie.dunn@hollyfrontier.com]
Sent: 10/31/2017 8:41:38 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Natalie Dunn
300 Morrie Ave
Cheyenne, WY 82007

Message

From: Sara Starr [sara.starr@hollyfrontier.com]
Sent: 10/31/2017 8:41:38 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Sara Starr
3010 State Street
Dallas, TX 75204

Message

From: Lorraine Martinez [Lorraine.Martinez@HollyFrontier.com]
Sent: 10/31/2017 8:41:37 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

Lorraine Martinez
300 Morrie Ave
Cheyenne, WY 82007

Message

From: Tony Conetta [anthony.conetta@hollyfrontier.com]
Sent: 11/3/2017 1:43:51 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Tony Conetta
4815 E 112th Pl
Tulsa, OK 74137

Message

From: Tim McKinney [timothy.mckinney@hollyfrontier.com]
Sent: 10/31/2017 3:41:18 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Tim McKinney
11731 S Vine St
Jenks, OK 74037

Message

From: Chris Smith [christopher.smith2@hollyfrontier.com]
Sent: 10/31/2017 8:41:37 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

Chris Smith
1330 W 375 N Apt F207
Centerville, UT 84014

Message

From: Michelle Caudle [michelle.caudle@hollyfrontier.com]
Sent: 12/4/2017 3:34:07 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Michelle Caudle
P.O. Box 1572
Mannford, OK 74044

Message

From: Mike Hanlon [michael.hanlon@hollyfrontier.com]
Sent: 10/31/2017 3:40:51 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

Mike Hanlon
12825 E Cherry Creek Ct
Wichita, KS 67230

Message

From: Michael Bones [Michael.Bones@hollyfrontier.com]
Sent: 10/31/2017 3:39:42 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

Michael Bones
1218 East 30th Place
Tulsa, OK 74114

Message

From: Frank Bernardo [frank.bernardo@hollyfrontier.com]
Sent: 10/31/2017 3:38:20 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

Frank Bernardo
926 Emerald Blvd
Southlake, TX 76092

Message

From: Jared Boatman [jared.boatman@hollyfrontier.com]
Sent: 10/31/2017 7:09:39 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Jared Boatman
117 W BLEVINS RD
ARTESIA, NM 88210

Message

From: Sean Dobbins [Sean.Dobbins@HollyFrontier.com]
Sent: 10/31/2017 3:38:19 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

Sean Dobbins
580 W 3rd St
Andover, KS 67002

Message

From: Paige Kester [paige.kester@hollyfrontier.com]
Sent: 10/31/2017 3:37:58 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Paige Kester
116 Londonberry Terrace
Southlake, TX 76092

Message

From: Wossen Abebe [wossen.abebe@hollyfrontier.com]
Sent: 10/31/2017 3:37:09 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Wossen Abebe
2828 N Harwood
Dallas, TX 75201

Message

From: Kyle Cavins [kyle.cavins@hollyfrontier.com]
Sent: 10/31/2017 3:36:55 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Please, help save our jobs and make this right. Please move the point of obligation for the RFS (Docket ID No. EPA–HQ– OAR–2017–0091) in a way that fixes this inequity.

Thank you.

Kyle Cavins
1731 S Canton Ave
Tulsa, OK 74112

Message

From: Gregory Tutak [greg.tutak@hollyfrontier.com]
Sent: 10/31/2017 3:36:38 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Gregory Tutak
1219 S 15th St
Artesia, NM 88210

Message

From: Jessica Simer [jessica.simer@hollyfrontier.com]
Sent: 10/31/2017 3:36:22 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Jessica Simer
3311 W Richey
Artesia, NM 88210

Message

From: Eric Sanders [eric.sanders@hollyfrontier.com]
Sent: 10/31/2017 6:11:38 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Eric Sanders
Rural Route 2 Box 257
Nowata, OK 74048

Message

From: Diane Davis [diane.davis@hollyfrontier.com]
Sent: 10/31/2017 5:23:07 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Diane Davis
2102 W Centre Ave
Artesia, NM 88210

Message

From: Todd Upshaw [Todd.Upshaw@Hollyfrontier.com]
Sent: 11/2/2017 6:33:23 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Todd Upshaw
10710 East 98th St. N
Owasso, OK 74055

Message

From: Robert Sharp [robert.sharp@hollyfrontier.com]
Sent: 11/14/2017 4:31:46 AM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Robert Sharp
11376 SW 50TH
TOWANDA, KS 67144

Message

From: Kevin Crockett [kevin.crockett@hollyfrontier.com]
Sent: 10/31/2017 5:05:44 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Kevin Crockett
55 W. Crockett Road
Lovington, NM 88260

Message

From: Cody gary [Cody.Gary@hollyfrontier.com]
Sent: 11/2/2017 6:03:27 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Cody gary
796 North Lone pine drive
Cleveland, OK 74020

Message

From: Constance Chan [constance.chan@hollyfrontier.com]
Sent: 10/31/2017 5:01:14 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Constance Chan
2828 N Harwood St Ste 1300
Dallas, TX 75201

Message

From: Dravis, Samantha [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ECE53F0610054E669D9DFFE0B3A842DF-DRAVIS, SAM]
Sent: 1/9/2018 8:49:21 PM
To: Burhop, Anna [anna.burhop@bracewell.com]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
CC: Krenik, Edward [edward.krenik@bracewell.com]; Lee, John [john.lee@bracewell.com]
Subject: RE: Chloroprene RfC

Flag: Follow up

Hi Anna, I have some time on Friday or next week. Can you coordinate with Robin Kime (copied).

I hope things are going well for you there, please give my best to Scott!

From: Burhop, Anna [mailto:anna.burhop@bracewell.com]
Sent: Tuesday, January 09, 2018 2:17 PM
To: Dravis, Samantha <dravis.samantha@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>
Cc: Krenik, Edward <edward.krenik@bracewell.com>; Lee, John <john.lee@bracewell.com>
Subject: Chloroprene RfC

Samantha and Brittany,

Since joining Bracewell, I have been working on a Request for Correction of the 2010 IRIS Review of Chloroprene. The IRIS Review contains errors and flawed science. We have met with ORD and the Office of the Administrator on this, and would like to brief you both on this as well. Do y'all have some time later this week or next for my colleagues, Ed Krenik and John Lee, and I to come meet with you?

Attached is the letter DPE sent to Administrator Pruitt last June explaining the request. I am also happy to share the full RfC with you.

Please let me know what times may work for your schedule. Feel free to give me a call if you have questions at 202.828.1728

Thank you!

Anna

ANNA BURHOP
Principal
anna.burhop@policyres.com
T: +1.202.828.1728 | F: +1.800.404.3970

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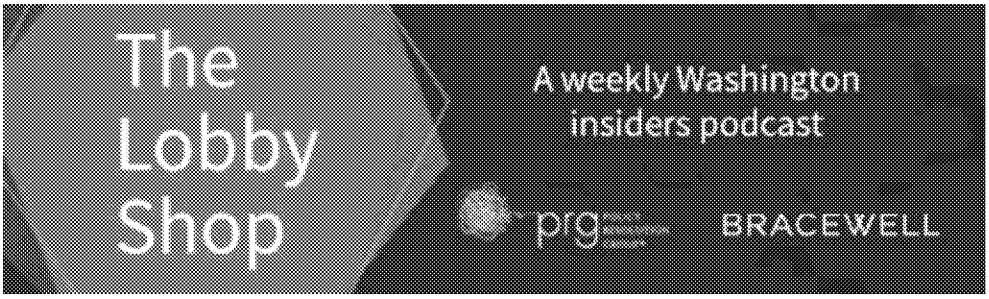

Message

From: efren hernandez [efren.hernandez@hollyfrontier.com]
Sent: 11/13/2017 6:57:46 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

efren hernandez
3110 n. 3rd street
lovington, NM 88260

Message

From: Lyle HGoffman [lyle.hoffman@hollyfrontier.com]
Sent: 10/31/2017 4:43:13 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Lyle HGoffman
1070 w 500 s
woods cross, UT 84087

Message

From: Troy McLaughlin [troy.mclaughlin@hollyfrontier.com]
Sent: 11/13/2017 5:23:27 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Troy McLaughlin
1110 McCollum Rd,
El Dorado, KS 67042

Message

From: Melva Tollett [melva.tollett@hollyfrontier.com]
Sent: 10/31/2017 4:31:05 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Melva Tollett
2828 N. Harwood, Ste. 1300
Dallas, TX 75201

Message

From: Randie Jones [randie.jones@hollyfrontier.com]
Sent: 10/31/2017 4:28:01 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

Randie Jones
1070 W 500 S
West Bountiful, UT 84087

Message

From: John Thurman [John.Thurman@hollyfrontier.com]
Sent: 10/31/2017 4:27:14 PM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
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Thank you.

John Thurman
1109 Mahone
Artesia, NM 88210

Message

From: Thomas Mefford [thomas.mefford@hollyfrontier.com]
Sent: 11/2/2017 11:34:37 AM
To: Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]
Subject: Help Protect Refiners Jobs In Reference to Docket ID No. EPA–HQ– OAR–2017–0091

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Thank you.

Thomas Mefford
2620 Overcrest Lane
Sapulpa, OK 74066

Message

From: Bolen, Brittany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31E872A691114372B5A6A88482A66E48-BOLEN, BRIT]
Sent: 3/8/2018 1:08:34 AM
To: Beau Greenwood [BGreenwood@croplifeamerica.org]
CC: James McVaney [james.mcvaney@bayer.com]; Fred Bosco [FBosco@croplifeamerica.org]
Subject: RE: Meet w/Bayer

Hello -
It is unclear why the email chain below depicts me as the sender as I sent no such email today. I had no knowledge of the email and it is not in my sent box. I presently have several staff who have ownership access to my calendar and email, and will follow up with them to take necessary steps to avoid this sort of issue moving forward.
Thank you,
Brittany

-----Original Message-----
From: Beau Greenwood [mailto:BGreenwood@croplifeamerica.org]
Sent: Wednesday, March 7, 2018 6:51 PM
To: Bolen, Brittany <bolen.brittany@epa.gov>
Cc: James McVaney <james.mcvaney@bayer.com>; Fred Bosco <FBosco@croplifeamerica.org>
Subject: Re: Meet w/Bayer

Ha! I look forward to our visit next week.

Beau.

> On Mar 7, 2018, at 9:40 AM, Bolen, Brittany <bolen.brittany@epa.gov> wrote:
>
> Beau, looks like the heavies are coming.
>
>
> Sent from my iPhone
>
> Begin forwarded message:
>
>
> From: "Bolen, Brittany" <bolen.brittany@epa.gov<mailto:bolen.brittany@epa.gov>>
> To: "Dravis, Samantha" <dravis.samantha@epa.gov<mailto:dravis.samantha@epa.gov>>, "Beck, Nancy" <Beck.Nancy@epa.gov<mailto:Beck.Nancy@epa.gov>>, "Inge, Carolyn" <Inge.Carolyn@epa.gov<mailto:Inge.Carolyn@epa.gov>>, "Luke Tomanelli" <luke.tomanelli@bayer.com<mailto:luke.tomanelli@bayer.com>>
> Subject: Meet w/Bayer
>
>
>
> Directions: Please use the William Jefferson Clinton North Entrance located on your right as you exit the Federal Triangle Metro Station. Please arrive 10 minutes prior to the meeting with photo IDs to clear security.
>
> EPA Contact: For an escort from security to the meeting, please call (202) 564-4332; for all other matters, please call Robin Kime (202) 564-6587.
> <meeting.ics>

Message

From: Bolen, Brittany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31E872A691114372B5A6A88482A66E48-BOLEN, BRIT]
Sent: 5/24/2017 10:59:12 PM
To: Traci Kraus [traci.kraus@cummins.com]
CC: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Kime, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ef7b76087a6475b80fc984ac2dd4497-RKime]
Subject: RE: Introduction

Hi Traci,

It was nice to meet you, too. Thank you for your email. I was in a meeting with Mike today and he mentioned your visit last week. I would be interested in hearing about your regulatory reform ideas. Please work with Robin to schedule a time to discuss.

Best,

Brittany

From: Traci Kraus [mailto:traci.kraus@cummins.com]
Sent: Wednesday, May 24, 2017 3:30 PM
To: Bolen, Brittany <bolen.brittany@epa.gov>
Cc: Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>
Subject: Introduction

Hi Brittany,

It was great to meet you at the Chamber meeting yesterday morning. I really appreciated hearing your perspective on all of the opportunities you and your team have at the agency. As we discussed, I work at Cummins and lead our government relations efforts on energy and environment issues, including truck and engine regulation for fuel efficiency and NOx.

I also mentioned that my colleague, Brian Mormino, was in town for meetings with the White House and your colleagues Ryan and Mandy (cc'd) at EPA to discuss some of these issues. I know we wanted to follow up with Mandy and keep you all in the loop on our discussions with the WH (Mike Catanzarro) regarding potential regulation streamlining and next-tier NOx, and I wanted to see if you might have time for a 30 minute meeting or call with me and Brian to fill you in on discussions.

Please let me know if this may be of interest to you.

Thanks so much!

All the best,

Traci Kraus
Director, Government Relations
Cummins Inc.

601 Pennsylvania Ave. NW

Suite 1100N
Washington, DC 20004
Office: 202-654-4285
Cell: Ex. 6

Message

From: Bolen, Brittany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31E872A691114372B5A6A88482A66E48-BOLEN, BRIT]
Sent: 5/23/2017 1:51:09 AM
To: Jay Cranford [cranford@cgcn.com]
CC: Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]; Kime, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ef7b76087a6475b80fc984ac2dd4497-RKime]; Katie Mitchell [mitchell@cgcn.com]
Subject: Re: meeting request

Hi Jay, we're happy to meet with Shea. Please coordinate with Robin on scheduling.
Best,
Brittany

On May 22, 2017, at 12:35 PM, Jay Cranford <cranford@cgcn.com> wrote:

> Good afternoon team. I'm emailing to request a meeting with Shea Loper (Encana) to discuss a few regulatory reform-related issues, including OOOOa; the 2015 ozone standard; and, improving enforcement approach.
>
> Shea will be in town and available on Tuesday, June 6 and Wednesday, June 7.
>
> Thanks for considering. -Jay

JAY CRANFORD | CGCN GROUP
1101 K STREET, NW, SUITE 650 WASHINGTON, D.C. 20005
202.689.9296 / cranford@cgcn.com / www.cgcn.com

Message

From: Bolen, Brittany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31E872A691114372B5A6A88482A66E48-BOLEN, BRIT]
Sent: 5/19/2017 7:10:05 PM
To: Prero, Judah [jprero@sidley.com]
Subject: RE: Invitation to ABA event

Hi Judah,

Thanks for the kind note. I knew David would do well. I wish I could have participated, please keep me in mind for future events.

Best,
Brittany

From: Prero, Judah [mailto:jprero@sidley.com]
Sent: Friday, May 19, 2017 11:10 AM
To: Bolen, Brittany <bolen.brittany@epa.gov>
Subject: RE: Invitation to ABA event

Brittany - wanted to thank you for your help with our event and arranging for David to come. He was great and the group really appreciated getting to hear from him and to meet him.

All the best,

Judah

JUDAH PRERO
Counsel

SIDLEY AUSTIN LLP
202 736 8451 office
Ex. 6 cell

From: Bolen, Brittany <bolen.brittany@epa.gov>
Date: Monday, May 08, 2017, 10:42 AM
To: Prero, Judah <jprero@sidley.com>
Cc: Fotouhi, David <fotouhi.david@epa.gov>
Subject: RE: Invitation to ABA event

Hi Judah,

Thank you for the invitation. Unfortunately, I am unavailable that morning. I found an excellent substitute – my colleague, David Fotouhi (cc'd). David is Deputy General Counsel and plays a key role in our regulatory reform efforts.

Best,

Brittany

Brittany Bolen
Deputy Associate Administrator, Office of Policy
U.S. Environmental Protection Agency
(202) 564-3291
Bolen.Brittany@epa.gov

From: Prero, Judah [mailto:jprero@sidley.com]
Sent: Monday, May 8, 2017 9:44 AM
To: Bolen, Brittany <bolen.brittany@epa.gov>
Subject: RE: Invitation to ABA event

Just checking to confirm receipt of the e-mail.

Thanks,

Judah

JUDAH PRERO*
Counsel

SIDLEY AUSTIN LLP
+1 202 736 8451
jprero@sidley.com
**Admitted only in Maryland and New York; pending approval of application for admission to the DC Bar, practicing law in the District of Columbia under the supervision of principals of the firm who are members in good standing of the DC Bar.*

From: Prero, Judah
Sent: Thursday, May 04, 2017 10:04 AM
To: 'bolen.brittany@epa.gov' <bolen.brittany@epa.gov>
Subject: Invitation to ABA event

Ms. Bolen,

On behalf of the American Bar Association's Section on Environment, Energy and Resources (SEER) Pesticide Chemical Regulation and Right to Know (PCRRTK) committee, I would like to invite you to be the guest speaker at our next "Friday Forum" event, scheduled for Friday, May 17, 2017, at the offices of Sidley Austin, 1501 K Street, NW, Washington DC, at 9 am.

Friday Forum events are an opportunity for the attorneys in the section to hear directly from government officials, policy makers, legislators, and industry leaders in an informal and intimate setting. It allows for the audience and the speakers to discuss environmental issues, ask questions of each other, and exchange thoughts and ideas. All Friday Forums are closed to the press and media in order to promote an open and frank discussion amongst speakers and participants.

We would welcome hearing from you on the subject of regulatory reform at EPA in general, and if you would like to discuss how reforms would specifically impact or address the TSCA and FIFRA related programs, we would welcome that discussion as well.

We hope you will be able to join us. Please feel free to be in touch with me if you have any questions, whether substantive or logistical in nature, about the program.

Thank you for the consideration.

Sincerely yours,

Judah Prero

JUDAH PRERO*
Counsel

SIDLEY AUSTIN LLP
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Washington, DC 20005
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jprero@sidley.com
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SIDLEY

**Admitted only in Maryland and New York; pending approval of application for admission to the DC Bar, practicing law in the District of Columbia under the supervision of principals of the firm who are members in good standing of the DC Bar.*

Message

From: Bolen, Brittany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31E872A691114372B5A6A88482A66E48-BOLEN, BRIT]
Sent: 4/20/2017 3:59:24 PM
To: Katie Mitchell [mitchell@cgcn.com]; Gunasekara, Mandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=53d1a3caa8bb4ebab8a2d28ca59b6f45-Gunasekara,]
CC: Jay Cranford [cranford@cgcn.com]; Kime, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ef7b76087a6475b80fc984ac2dd4497-RKime]
Subject: RE: meeting request

Thanks, Katie. Robin will be in touch to confirm a time.

From: Katie Mitchell [mailto:mitchell@cgcn.com]
Sent: Thursday, April 20, 2017 11:09 AM
To: Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>
Cc: Jay Cranford <cranford@cgcn.com>
Subject: RE: meeting request

Mandy/Brittany – I just spoke with Boeing, below are the best times! I would also like to clarify that Ted Austell, VP of Executive, Legislative, and Regulatory Affairs at Boeing will also plan to join Peter Pagano and Jay Cranford in this meeting.

Wednesday, April 26 – 10:30am-11:30am, 2:30pm-5:00pm

Please let us know what works best with your schedule. Thank you both!

KATIE MITCHELL | CGCN GROUP
1101 K STREET, NW, SUITE 650 WASHINGTON, D.C. 20005
559.623.6303 / mitchell@cgcn.com / www.cgcn.com

From: Jay Cranford
Sent: Thursday, April 20, 2017 6:16 AM
To: Gunasekara, Mandy <gunasekara.mandy@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>
Cc: Katie Mitchell <mitchell@cgcn.com>
Subject: Re: meeting request

Mandy, let me check with Boeing about that date/time and I will get back to you today. Thank you. -Jay

Jay Cranford
CGCN Group
202.689.9296
www.cgcn.com

From: Gunasekara, Mandy <gunasekara.mandy@epa.gov>
Sent: Wednesday, April 19, 2017 7:22 PM
Subject: RE: meeting request
To: Jay Cranford <cranford@cgcn.com>, Bolen, Brittany <bolen.brittany@epa.gov>
Cc: Katie Mitchell <mitchell@cgcn.com>

Jay,

Great to hear from you and happy to meet on these issues. Does next Wednesday (4/26) work? I'm fairly flexible that day.

Best,
Mandy

From: Jay Cranford [mailto:cranford@cgcn.com]
Sent: Tuesday, April 18, 2017 12:48 PM
To: Gunasekara, Mandy <Gunasekara.Mandy@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>
Cc: Katie Mitchell <mitchell@cgcn.com>
Subject: meeting request

Good afternoon team. I'm reaching out on behalf of our client, Boeing, to request a meeting to discuss a few issues they are following, including fuel efficiency standards and ICAO.

Peter Pagano (Boeing) and I would be attending from our end.

Thanks for considering. -Jay

JAY CRANFORD | CGCN GROUP
1101 K STREET, NW, SUITE 650 WASHINGTON, D.C. 20005
202.689.9296 /cranford@cgcn.com /www.cgcn.com

Message

From: Bolen, Brittany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=31E872A691114372B5A6A88482A66E48-BOLEN, BRIT]
Sent: 7/14/2017 1:24:32 AM
To: Lacey, Pam [PLacey@aga.org]
CC: Inge, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f763e42702a4f468cdf42323ee94520-Cinge]; Kime, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ef7b76087a6475b80fc984ac2dd4497-RKime]
Subject: Re: Follow up meeting re: AGA and NGVA Regulatory Reform Comments (EPA-HQ-OA-2017-0190)

Hi Pamela,
Thank you for your email and for sharing your comments filed. Please work to Carolyn (cc'd) to see if there is a time that works to meet with Samantha and I.
Best,
Brittany

> On Jul 13, 2017, at 5:22 PM, Lacey, Pam <PLacey@aga.org> wrote:
>
> Dear Ms. Bolen:
>
> It appears my email of June 28th may not have been delivered to you. Please see my note below and let me know whether you are available to meet next week, or if not, please suggest some dates in August that could work. AGA and NGVA would like to discuss EPA regulatory reform ideas with you and Ms. Dravis.
>
> Best regards,
>
> Pamela A. Lacey | Chief Regulatory Counsel
> American Gas Association<http://www.aga.org>
> 400 N. Capitol St., NW | Washington, DC | 20001
> P: 202-824-7340 | M: Ex. 6 | F: 202-824-9190 | placey@aga.org <mailto:placey@aga.org>
>
> The American Gas Association represents more than 200 local energy companies committed to the safe and reliable delivery of clean natural gas to more than 69 million customers throughout the nation.
> From: Lacey, Pam
> Sent: Wednesday, June 28, 2017 2:03 PM
> To: Samantha Dravis (Dravis.samantha@Epa.gov) <Dravis.samantha@Epa.gov>; 'bolen.brittany@epa.org' <bolen.brittany@epa.org>
> Cc: Clarke, Jeff <jclarke@ngvamerica.org>; Cunningham, Allison <ACunningham@ngvamerica.org>
> Subject: Follow up meeting re: AGA and NGVA Regulatory Reform Comments (EPA-HQ-OA-2017-0190)
>
> Dear Ms. Dravis and Ms. Bolen:
>
> The American Gas Association (AGA) and Natural Gas Vehicles of America (NGVA) would like to arrange a follow-up meeting with you to discuss our ideas for regulatory reform, as described in our attached comments, filed May 15, 2017 in Docket EPA-HQ-OA-2017. NGVA General Counsel Jeffrey Clarke and NGVA Federal Government Affairs Director Allison Cunningham and I would like to meet with you and your team in July.
>
> We are available anytime on Thursday July 14, the afternoon of Friday July 15, and anytime in the week of July 17-21 (other than 10:30 am – 1 pm on July 19 and 20. Please let me know what date and time you would prefer.
>
> Respectfully,
>
> Pamela A. Lacey | Chief Regulatory Counsel
> American Gas Association<http://www.aga.org>
> 400 N. Capitol St., NW | Washington, DC | 20001
> P: 202-824-7340 | M: Ex. 6 | F: 202-824-9190 | placey@aga.org <mailto:placey@aga.org>
>
> The American Gas Association represents more than 200 local energy companies committed to the safe and reliable delivery of clean natural gas to more than 69 million customers throughout the nation.
> <AGA 05 15 2017 Comments on EPA Rule Review Docket EPA-HQ-OA-2017-0190.pdf>
> <NGVA EPA Regulatory Review May 2017 Final.pdf>